EXHIBIT 2

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	: MDL NO. 2875 : VIDEOTAPED DEPOSITION : UPON : ORAL EXAMINATION : OF : RAMIN (RON) NAJAFI, Ph.D.

TRANSCRIPT of the stenographic notes of the proceedings in the above-entitled matter, as taken by and before ELLEN J. GODINO, CCR, RPR, CRCR, held via ZOOM VIDEOCONFERENCE from various locations, with the witness located at 1000 Atlantic Avenue, Suite 110, Alameda, California, on Wednesday, January 18, 2023, commencing at 9:10 Pacific Time.

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I N D E X

EXHIBITS

E X H I B I T S (Continued)

E X H I B I T S (Continued)

REQUESTS

Page	Line
81	24

THE VIDEOGRAPHER: We are going on the record at 9:10 on January 18, 2023. This is Media Unit Number 1 of the video-recorded deposition of Ron Najafi regarding the valsartan litigation.

My name is Justin Bily representing Veritext, and I'm the videographer. The court reporter is Ellen Godino from the same firm.

All counsel will be noted on the stenographic record.

Will the court reporter please swear in the witness and then we can begin.

RAMIN (RON) NAJAFI, Ph.D., 1000 Atlantic Avenue, Suite 110, Alameda, California, having been duly sworn, testified as follows:

EXAMINATION BY MS. ROSE:

Q. Hi, Dr. Najafi. My name is Nina Rose, and I represent the ZHP defendants in this case.

Can you please state your full name for the record.

MS. ROSE: I'm having a hard time hearing. Can anyone else hear?

MR. NIGH: I can't hear him either.

THE WITNESS: Can you hear me?

MR. NIGH: Yes. Now we can.

Page 10

THE WITNESS: It's Ramin Ron Najafi.
Q. Dr. Najafi, as you know, this deposition is being conducted remotely via an online platform.
Have you performed a test of the platform that we're using to conduct this deposition prior to today?
A. Yes, I have.
Q. Is there anyone in the room with you where you are testifying today?
A. No.
Q. Can anyone other than the online participants to this deposition hear your testimony today?
A. No.
Q. Are you participating on this deposition using your computer audio and microphone?
A. Yes, I am.
Q. Do you have a telephone line available in case there's a problem with your audio?
A. I do. In fact, I can -- if you give me a number, I would actually rather use the phone, so I can call in.
MS. ROSE: I can hear you fine.
If -- Daniel, if you want to stop and

Page 11

go off and change platforms, we can.
MR. NIGH: I can hear you fine too, Dr. Najafi.
THE WITNESS: Okay. Then let's continue. But if a problem arises, I have a phone next to me.
MS. ROSE: Perfect. Thank you.
Q. Dr. Najafi, I know you've been deposed in this litigation and others.
So is it safe to say you know the basic rules of a deposition?
A. Yes, I do.
Q. All right. I'll save time and not run through them all, but if we can remember not to talk over one another, if you can let me finish my questions before you answer, I will do my best to let you finish your answers before I ask a new question. Fair?
A. Yes.
Q. I will, for the court reporter, attempt to speak slowly, especially when reading from documents, so she can get every word. Because we are doing this deposition remotely, there's a few things I want to discuss.
Aside from Zoom, do you have any other

Page 12

software open on your computer right now?
A. No.
(Court Reporter Clarification.)
THE WITNESS: Let me switch to phone, I think, because otherwise, I'll be shouting.
MS. ROSE: Okay. Let's go off the record.
THE VIDEOGRAPHER: The time is 9:13. Going off the record.
(A brief recess takes place.)
THE VIDEOGRAPHER: The time is 9:17. We're back on the record.
BY MS. ROSE:
Q. Okay. Dr. Najafi, just to clarify, you are now connected to the deposition on your telephone. Correct?
A. Yes, it is.
Q. Okay. And I'm not sure if we got through this question before.
You don't have any email or messaging software open on your computer. Correct?
A. No, I don't.
Q. Will you agree not to open any software on your computer aside from Zoom while we are on the record during this deposition?

Page 13

A. Yes, I do.
Q. Do you have any documents or other files open on your computer?
A. No.
Q. We're going to look at some documents today on Zoom, and aside from those documents, will you agree not to look at any other electronic files while we are on the record for this deposition?
A. I do.
Q. Will you agree not to have any private communications while we are on the record during the deposition?
A. Yes, I do.
Q. Have you had any alcoholic drinks in the past eight hours?
A. No.
Q. Are you on any medication today that might interfere with your ability to give accurate testimony?
A. No, I'm not.
Q. Is there any other reason you cannot give complete and accurate testimony here today?
A. No.
Q. Dr. Najafi, you first submitted a report in this case in November 2021. Correct?

Page 14

A. I believe so.
Q. Is it okay with you if I refer to that as your initial report or your 2021 report today?
A. Sure.
Q. And you gave a deposition about your initial report in February of 2022. Correct?
A. Restate your question.
Q. Am I correct that you gave a deposition about your initial report in February 2022?
A. No.
Q. Have you given a deposition?
A. February -- February 2022 on valsartan?
Q. Yes.
A. I don't recall.
Q. Do you recall giving a prior deposition on valsartan?
A. Yes, I do.
Q. Do you recall what year it was in?
A. I think it was 2021.
Q. Okay. We'll get there, but how about just for purposes of clarity, I'll refer to your last deposition --
A. Yes.
Q. -- to refer to the prior deposition you gave. Is that okay?

Page 15

A. Sure.
Q. And since your last deposition, you submitted a second report on October 31st, 2022. Correct?
A. Yes.
Q. Is it fair to say that that's a more in-depth report setting forth all your opinions in this case?
MR. NIGH: Form objection.
A. Two different reports.
Q. Would you say that your current report contains all of the opinions in your 2021 report plus additional opinions?
A. Yes, I would say so.
Q. Do you intend to offer any opinions in this case that are not included in your October 2022 report?
MR. NIGH: Form objection.
A. I may have other opinions depending on topic.
Q. Okay. What opinions not included in your October 31st, 2022, report do you intend to offer in this case?
MR. NIGH: Form objection.
A. Currently, I don't have any, but if

Page 16

something comes up and I'm asked to offer an opinion, then I would.
Q. Okay. But as of today, you intend to only offer the opinions that are provided in your October 31st, 2022, report?
A. That's correct, that's my latest opinion.
Q. Is it fair to say that in addition to your personal experience, your opinions in this case are based on the materials cited in your October 2022 report and the list of materials considered that was included with that report?
A. Yes.
Q. Did you rely or consider any other materials not identified in your current report?
A. No.
Q. I'd like to bring up and introduce Tab 1.
(Exhibit Najafi-1, Defendants' Notice of Videotaped Deposition of Ron Najafi was received and marked for identification.)
Q. Dr. Najafi, have you seen this document before?
A. I have to -- can you make it bigger?
MR. NIGH: I'm actually not seeing this

Page 17

document yet in the test exhibits.
THE VIDEOGRAPHER: You may just have to refresh.
MR. NIGH: Okay.
A. I haven't seen this, no.
MR. NIGH: Dr. Najafi, were you able to load this document up on your other screen?
THE WITNESS: No.
MR. NIGH: Because you can navigate through the document too, as opposed to asking to make it bigger and where to go.
THE WITNESS: Right. How do I -- how do I load it into --
MS. ROSE: Counsel -- I'm sorry. I'm sorry to interrupt, Dr. Najafi. Why don't we go off the record while we get the text right on this. We can do it for this first exhibit, and then we'll be good to go for the rest of the deposition.
THE VIDEOGRAPHER: The time is 9:23. We're going off the record.
(A brief recess takes place.)
THE VIDEOGRAPHER: The time is 9:24. We're back on the record.
BY MS. ROSE:
Q. Okay. Dr. Najafi, have you seen this

Page 18

document before?
A. Yes, I have.
Q. When did you last see it?
A. I've seen so many documents. I think this is a notice -- this is a notice of today's deposition.
Q. Okay. And if you --
MS. ROSE: Justin, if we go to page 5 of the document to Request 6. We're actually going to go to the next page.
Q. This is a request for your complete and entire file for this case, including -- and then if you go down to Subsection (c), it says: "All materials and documents that you have reviewed at any time and from any source that relate to the facts of this case, your opinions in this case, valsartan or nitrosamines."
Do you see that?
A. Which page? Page 6?
Q. If you look at the screen on your first screen.
Do you see that language?
A. Page 6.
Q. Page 6, Subsection (c)?
A. Correct. Got it. Yeah. Yeah, you

Page 19

have -- prepared. Yeah, okay.
Q. Did anyone ask you to produce documents responsive to this request?
A. Did anyone -- would you repeat your question.
Q. Sure. Did anyone ask you to produce documents to the defendants that are responsive to this request prior to your deposition today?
A. No.
Q. All right.
MS. ROSE: We can take the document down, Justin.
Q. I believe you previously testified that you have never worked at FDA. Is that correct?
A. That's correct.
Q. And you still have not done any consulting work for the FDA. Is that correct?
A. That's correct.
Q. Have you ever been to the FDA headquarters?
A. Yes, I have.
Q. When was that?
A. In 2006, 2008, you know, 2012, you know, multiple times.
Q. And what was the purpose for those

Page 20

visits, generally?
A. We're -- we were developing drugs, and we had multiple meetings with the FDA around our investigation on new drug application.
Q. And were any of those drugs pharmaceuticals API?
A. Yes, they were.
Q. Do you recall which pharmaceutical APIs?
A. Investigational drugs, it's called NVC-422.
Q. Sorry, is NVC-422 -- that's the name of the investigational drug?
A. That's -- the name of the investigational drug is N like Nancy, V like Victor, C like Charlie, dash, 422.
Q. And was that API ever used in a drug that was released on the market?
A. No.
Q. Was a DMF, or drug master file, submitted for that API?
A. No.
Q. And that API was manufactured by a company for which you worked. Is that correct?
A. We were the -- we were contracting this

Page 21

out to a contract manufacturer.
Q. Sorry, are you done? I couldn't tell if you were pausing or done with your answer.
A. I'm done.
Q. Okay. So you -- your company and -- I'll back up.
Who was the company you were working for at the time?
A. It's a Swiss company called Carbogen.
Q. And were you employed there?
A. No. They were -- I had hired them to manufacture our API under cGMP.
Q. Okay. When you say "our API," who is the "our" you are referring to there?
A. My company, NovaBay Pharmaceuticals.
Q. And roughly what year was that? Or years?
A. I think 2000 -- late 2007, 2007, 2008, 2012. We made multiple batches, you know, multiple manufacturing lots.
Q. But your company, NovaBay Pharmaceuticals, did not manufacture the API. It was manufactured by a contract company. Is that correct?
A. So on record, we are responsible for

Page 22

the manufacturing of our API, so we contracted out the procedure and the methodology to manufacture to Carbogen, and Carbogen was our contract manufacturer. This is done very often in our industry.

Q. Did NovaBay Pharmaceuticals actually manufacture any -- sorry, actually manufacture any pharmaceutical API?

A. No.

Q. Do you have friends or colleagues who work or have worked for the FDA?

A. Yes.

Q. Do you hold them in high regard professionally?

A. I do.

Q. Would you agree that the FDA is statutorily charged with protecting the public health by ensuring that pharmaceutical drugs are safe and effective?

MR. NIGH: Form objection.

A. Can you be more specific?

Q. Sure. I just -- do you agree that there is a statute that charges the FDA with protecting the public health by ensuring that pharmaceutical drugs are safe and effective?

Page 23

MR. NIGH: Form objection.

A. I presume so; that's the goal.

Q. I'm sorry. I think I spoke over you.

A. I said that's their goal. That's their objective.

Q. Okay.

MS. ROSE: Ellen, I just wanted to let you know. I think there's a little bit of a delay between the audio for Dr. Najafi. So there might be times where I think he's done and he's still speaking. So I apologize for that. I'll try to give him time so that we don't do that again; but if it's becoming a problem for you, let me know.

Q. Do you agree the FDA generally acts in the best interest of the public?

MR. NIGH: Form objection.

A. I agree.

Q. Are you aware that after nitrosamines were identified in valsartan in June of 2018, the FDA began an investigation of nitrosamine contamination of pharmaceuticals?

A. Yes, I am.

Q. Are you aware the FDA released a number of public statements updating the public on that investigation?

Page 24

A. Yes, I am.

Q. I'm going to introduce Tab 3.

(Exhibit Najafi-2, FDA News Release entitled, "FDA announces voluntary recall of several medicines containing valsartan following detection of an impurity," dated July 13, 2018, was received and marked for identification.)

Dr. Najafi, this is an FDA news release titled "FDA announces voluntary recall of several medicines containing valsartan following detection of an impurity."

Have you seen this document before?

A. Was this uploaded in our -- let me just take a look. Not uploaded to the -- to the documents.

Q. Have you hit refresh?

A. Hold on one second.

I am doing that. It's --

MR. NIGH: It just showed up for me.

A. Okay. Let me do it again.

FDA statement, okay, they're not in order, that's why. Okay. I'm looking at it. Just bear with me. I need to make it bigger a little bit. I don't have good eyesight anymore.

MS. ROSE: Can we go off the record for

Page 25

a second.

A. I have seen it.

Q. You have. I'm sorry. We'll start.

A. Go ahead. I have seen it.

Q. I was having a tech issue, but you've answered my question. You've seen it before. When?

A. Yeah.

Q. When did you first see this?

A. I can't recall; sometime -- sometime probably in 2019.

Q. Okay. Did you review it before you were retained in connection with valsartan litigation?

A. Yes, I have.

Q. But you don't cite this press release in your report or on your list of materials considered. Correct?

A. I don't recall if I have or I have not.

Q. Did you consider it in forming your opinions in this case?

A. I don't recall.

What is your specific question regarding this that I can answer?

Q. Oh, we'll get there, trust me. Trust

Page 26

me.
A. Okay.
Q. I have a variety of questions.
A. Right.
Q. So generally the press release addresses the identification of NDMA in valsartan API. Correct?
A. That's correct.
Q. And it also addresses the resulting voluntary recall of certain valsartan drug products. Correct?
A. That's correct.
Q. Are you aware of any previous statements by the FDA regarding the presence of nitrosamines in valsartan API or valsartan-containing drugs?
A. Am I aware of FDA's previous statement regarding valsartan -- nitrosamine in valsartan?
Q. Yes. This press release is dated July 13, 2018. Are you aware of any prior public statement by the FDA regarding the presence of nitrosamines in valsartan?
MR. NIGH: Form objection.
A. I don't know. I don't believe so.
Q. Okay. If we go to page 1, paragraph 1.

Page 27

The FDA states in the press release: "The presence of NDMA was unexpected and is thought to be related to changes in the way the active substance was manufactured."
Do you see that?
MR. NIGH: Dr. Najafi, you need to answer with a verbal response as opposed to nodding your head yes.
A. Sorry, let me take a look at this statement, if you don't mind.
Q. Sure. Just so you know, it's right up on the screen and it's highlighted.
A. Yeah, that's very useful. Thank you.
Nitrosamine -- I'm not going to read, sorry.
Yes.
Q. Okay. Do you agree with the statement by the FDA in 2018?
A. You know, there is -- you can have a lot of discussions around the presence of NDMA was unexpected and is thought to be related to changes in the way the active substance was manufactured. I think it's an accurate statement.
Q. I'm sorry, did you say an accurate statement or inaccurate statement?

Page 28

A. It is an accurate statement. It was -- it was unexpected by the defendants, that's correct, but the entire -- you know, my entire opinion is based on the fact that they should have expected it.
Q. Got it. Okay. Thank you.
Going to page 2, paragraph 5. The press release states: "The FDA will continue to investigate this issue and provide additional information when it becomes available."
Do you see that? It's right up on the screen.
Sorry, did you say you see that, Dr. Najafi?
A. Yes, I do. I see it.
Q. Great.
So in July 2018, a month after NDMA was identified in valsartan API, the FDA was still investigating how NDMA came to be in the product. Correct?
A. That's according to their statement. They are continuing their investigation on this issue and additional information when it becomes available.
Q. Thank you.
Dr. Najafi, are you aware that on

Page 29

August 30th of 2018, FDA Commissioner Dr. Scott Gottlieb issued another public statement on behalf of the FDA regarding nitrosamines and valsartan?
A. I don't know which one you're referring to. Can you show me the specific document you're talking about?
Q. You're -- we're in a mind meld. I'm about to go there.
MS. ROSE: We'll introduce Tab 4.
And, Justin, I don't think we've been marking as exhibits. So if we need to go back on a break, and we can do that, I believe at this point we're up to Exhibit 3?
THE VIDEOGRAPHER: Correct.
(Exhibit Najafi-3, FDA Statement entitled, FDA's ongoing investigation into valsartan impurities and recalls and an update on FDA's current findings, dated August 30, 2018, was received and marked for identification.)
MS. ROSE: Okay. How about in putting the documents up -- we can fix this on a break, but in putting the documents up in the folder for Dr. Najafi, we could limit -- is there any way to identify them as by the exhibit number? That might be helpful for him.

Page 30

THE WITNESS: I think that might be helpful.
MS. ROSE: We can talk about it on the next break.
Q. Okay. But in front of you now and should be on your folder is the August 30, 2018, FDA statement that I was just referring to.
Have you seen this before?
A. I believe I have, but if you don't mind, just for the sake of accuracy, could you put it up on my -- on --
THE WITNESS: Justin, if you could put it up so I can click on it and make it bigger.
MR. NIGH: Dr. Najafi, you can see it in your folder too. I don't know if that's what you're asking, but it's Tab 4 at the --
THE WITNESS: Yeah, in the folder.
MR. NIGH: Okay.
A. I see Tab 1. Okay, I see it, Tab 4. Okay.
Q. Okay. Do you see the document, Dr. Najafi?
A. Just one second.
Yeah, I have seen this document before.
Q. When was the first time you saw this

Page 31

document?
A. Months ago.
Q. Was it after you were retained in connection with this litigation?
A. I can't recall to the specific date and time.
Q. When you say "months ago," you were retained in connection with this litigation in 2019, I believe, so that would be about three or so years ago.
Have you seen this document since then?
A. Yes.
Q. You saw it for the first time after you were retained. Is that fair?
A. I can't recall. It could be before; it could be after.
Q. Did you consider this document in forming your opinions in this case?
A. Yes, I did consider this document. Yes.
Q. But you did not include this document in your list of materials considered or cited in your report. Correct?
MR. NIGH: Form objections.
A. I don't recall if I have or not.

Page 32

Q. Okay. If I represent to you that this document is not cited in your report or included on your list of materials considered, do you have a reason to take issue with that?
MR. NIGH: Form objection, that being an inaccurate representation.
A. What -- what is the specific question regarding this document?
Q. Oh, my question is whether you cited it in your report.
MR. NIGH: Form objection.
A. I may have or I may not. I can't recall.
MS. ROSE: Well, let's go to page 3 of the PDF at paragraph 2, where it starts "In St. Louis," third paragraph down.
Q. "In St. Louis the FDA maintains the most advanced pharmaceutical laboratory of any regulatory agency in the world."
Do you agree with that statement?
A. What is the -- you know, it really depends on whose definition is most advanced pharmaceutical laboratories.
Q. Do you agree --
A. I haven't visited --

Page 33

Q. I'm sorry. Go ahead, finish your answer.
A. I haven't visited their lab to see if they have a most advanced pharmaceutical laboratory. I can only take their word for it.
Q. Okay. Do you have any reason to dispute the FDA's claim that it has the most advanced pharmaceutical laboratory of any regulatory agency in the world?
MR. NIGH: Form objection.
A. That's what FDA says. You know, I take their word for it.
Q. The statement also states at three, paragraph 2: "As soon as we were aware of the NDMA impurity in certain valsartan drugs, we began collecting samples of all valsartan API and products marketed in the United States."
Do you see that? Do you see that what's on the screen?
A. Yes, I do.
Q. Do you have any reason to dispute that the FDA began collecting samples of valsartan to test after NDMA was identified in valsartan in June 2018?
MR. NIGH: Form objection.

Page 34

A. I have no reason to dispute that.
Q. It goes on to state: "At the same time our scientists began developing a test to detect and quantify NDMA in valsartan API."
Do you see that?
A. Yes, I do.
Q. Do you have any reason to dispute that the FDA began developing a test to detect NDMA in valsartan after June 2018?
MR. NIGH: Form objection.
A. Can you repeat your question?
Q. Do you have any reason to dispute this statement by the FDA, that it began developing a test to detect NDMA in valsartan after June 2018?
MR. NIGH: Form objection.
A. I have no way of knowing that, whether they did or they did not, but I take their word for it.
Q. The next sentence says: "NDMA's properties make it difficult to find."
Do you agree with Dr. Gottlieb, the head of the FDA, that NDMA's properties make it difficult to find?
MR. NIGH: Form objection.
A. What is the definition of -- what's

Page 35

your definition of "NDMA property makes it difficult to find"?
Q. My definition is not important. It's the FDA who is stating it. I'm just asking if you agree with that statement that was made by the FDA in 2018.
MR. NIGH: Form objection.
A. I disagree. I respectfully disagree with the FDA. I think it's -- that's a bad sentence to begin with. What do you mean to find? NDMA's property makes it difficult to find? Find what?
Q. Okay. So you respectfully disagree with the statement made by the head of the FDA that NDMA's properties make it difficult to find?
MR. NIGH: Form objection.
A. It's a vague statement, but I disagree with that.
Q. Moving to paragraph 3 of the same page. It says: "To determine if valsartan products do contain this impurity, CDER scientists have now developed the gas chromatography mass spectrometry (GCMS) headspace testing method. We posted this method to the Web to help manufacturers and regulators detect NDMA and valsartan API in tablets."

Page 36

Do you agree with the statement that the FDA developed the GCMS headspace method for manufacturers to use to detect NDMA in valsartan in the summer of 2018?
A. I take their word for it. They apparently posted a method for detecting NDMA to their website and to help the manufacturers, but what I need to elaborate is that detecting NDMA and analyzing NDMA has been done since late 1970s.
Q. But according to this statement by the FDA, the FDA developed the gas chromatography mass spectrometry testing method in June 2018.
MR. NIGH: Form objection.
A. That's what FDA stated. What I'm saying is that, you know, FDA is not the ultimate analytical expert on this -- on the planet. You know, NDMA analysis, you know, has been done since late seventies.
Q. Would you agree that the FDA had not identified a specific method to test for NDMA or NDEA prior to the summer of 2018?
A. Would you repeat again?
Q. Sure. Would you agree that the FDA had not identified publicly a specific method to test for NDMA or NDEA prior to the summer of 2018?

Page 37

A. I don't know.
Q. Do you know if the FDA --
A. What I can tell you -- if you don't mind, what I can tell you, not only NDMA was being analyzed in the seventies, which is really 50 years ago, prior to that, Novartis found NDMA and they had a method to analyze NDMA. And Novartis's subcontractors, Sovias, also was able to -- had a method to detect NDMA in -- by GCMS, by GC-FID. FDA was not the first body to come up with a method with the NDMA, if that's what you're asking.
Q. That wasn't what I was asking.
What I was asking was do you agree that the FDA had not mandated a specific method to use to test for NDMA or NDEA prior to the summer of 2018?
MR. NIGH: Form objection.
A. In my opinion, FDA is not the body that mandates testing. It's the manufacturers that need to do their testing, come up with the methodologies, et cetera, et cetera. It's really not FDA's responsibility to say what should be done or shouldn't be done.
Q. Do you agree that current 2022 -- now we're in 2023; I haven't caught up in years yet -- current FDA regulations and guidance provide for the

Page 38

use of GCMS testing to test for NDMA and NDEA?
A. I think as a result of valsartan and other -- pardon me. Let me actually turn off my phone.
As a result of nitrosamine situation, they have gotten involved, but, you know, the guidances -- there are plenty of guidances out there for genotoxic impurities and controlling and limiting genotoxic impurities by ICH, by FDA, by, you know, European regulatory bodies. You know, so there are plenty of guidances out there dating back to beginning of time.
Q. Okay. But I'm asking a very specific question, and I think you answered it in a roundabout way already.
The FDA had --
A. Okay.
Q. As of today, the FDA has adopted guidance regarding the use of GCMS testing for NDMA and NDEA. Correct?
A. They have now guidances, correct.
Q. Great.
But prior to the summer of 2018, the FDA, and only the FDA, had not adopted any guidances on using GCMS testing to detect NDMA or NDEA.

Page 39

Correct?
A. I think, you know, FDA reacts to matters that come before them, and in this case, they have come up with guidances. But typically manufacturers need -- tell FDA of how they're going to do their testing, what the testing entails and how they're going to be controlling genotoxic impurities, et cetera, and not the other way around.
Just to elaborate for the sake of better communication, when I go to the FDA around my API, I don't ask FDA how I should be testing my drug.
Q. Okay. I appreciate the elaboration and, again, I think maybe we have the answer, but I just want to clarify that we have it on record.
That prior to the summer of 2018, the FDA had not adopted guidance providing a method to detect for NDMA or NDEA in pharmaceutical substances. I believe you've said yes through your elaboration, but I just want to make sure that I'm clear so we're on the same page.
A. I said yes with qualifications, and it's a very important one, that --
Q. I appreciate the qualifications.
A. For us, you know, because FDA -- do you

Page 40

think FDA has a guidance for every genotoxic compound? No, they don't.
Q. Okay. We'll move on.
A. They don't.
Q. Let's look at page, on page 3 of the PDF, paragraph 5, that partially states: "... specifically a combination of conditions which include certain chemicals, processing conditions, and production steps could lead to formation of the NDMA impurity. We believe that these risks are introduced through a specific sequence of steps in the manufacturing process where certain chemical reactions are needed to form the active ingredient. Before we undertook this analysis, neither regulators nor industry fully understood how NDMA could form during this process."
Do you agree with the FDA commissioner, that before the FDA undertook its analysis following the identification of NDMA in valsartan in June of 2018, neither regulators nor industry fully understood how NDMA could form during the manufacturing process?
MR. NIGH: Form objection.
A. I'm trying to download this on my list. Is that Tab 4?

Page 41

Q. This is the same document we've been talking about. If we want to go off the record so you can look at the document in full for a few minutes and then talk about it, that's fine. I'm fine with that, but we haven't switched documents. We're on the same document we've been on.
A. Let's not go off the record because I'm not planning to be here all day.
Q. Okay. Well, you want some time to review the document?
A. Yeah.
Q. I appreciate that. I want to give you the time you need.
A. Right. So this is -- this is on the same document Dr. Gottlieb's press release you're talking about.
Q. I'm talking about the exact same document we've been talking about.
A. Okay.
Q. I'm talking about the July 2018 -- I'm sorry, August 2018. Same page that we've been looking at, the last paragraph in the page, on page 3.
A. Three, last paragraph, okay. Got it. I see it now.

Page 42

Q. Do you agree with the FDA's statement that is highlighted on the screen right now?
MR. NIGH: Form objection.
Q. Dr. Najafi, I'm going to ask to go off the record so you can review the document. I just don't want to waste time with reading documents.
MR. NIGH: Ms. Rose, I don't know if you know the ruling. If it's something where he's trying to read for five to ten minutes --
MS. ROSE: I don't think that's what the document -- sorry, what the ruling said. But also, we've been on the same document for a while, and it's just a sentence.
MR. NIGH: I would disagree. That is the ruling. So to try to go off the record 30 seconds after a question when he's trying to look at the document to answer the question I think is inappropriate.
THE WITNESS: And, Nina, if you keep bombarding me with questions, it interrupts me from reading that statement. I cannot accurately respond to you, you know -- you know, if we're off the record, but just please allow me, you know, like 60 seconds of no conversation so I can actually read the statement.

Page 43

MS. ROSE: Okay, Ellen, did we ever go off the record? We've been on the record this whole time?
I'll give you 30 seconds to read this one sentence.
A. You want to give me -- I appreciate 30 seconds of no conversation.
Q. Okay. Perfect.
A. I appreciate it.
Q. Dr. Najafi, I just timed on my phone 30 seconds. Are you comfortable talking about this?
A. Yeah, yes. So what's your specific question?
Q. To repeat my question, do you agree with the FDA commissioner's statement that prior to June of 2018, neither regulators nor industry fully understood how NDMA could form during the manufacturing process?
MR. NIGH: Form objection.
A. I respectfully disagree with the FDA's statement.
Q. Is it your position --
A. And I can explain, and I can explain why.
Q. I'm fine with your answer. You

Page 44

answered my question. Thank you.
Is it your position that the FDA should have known prior to the summer of 2018 that NDMA could form during the manufacturing process for valsartan API?
MR. NIGH: Form objection.
A. Not the responsibility of FDA to understand the process.
Q. Okay. Looking at paragraph 5 on pages 3 to 4 --
MS. ROSE: So actually, you can stay just where you are, Justin, the next sentence after the highlighted part -- you don't have to go anywhere else.
Q. "We are still not 100 percent sure that this is the root cause of the problem. Full understanding will require correlation of multiple test results from valsartan APIs made by different processes with the various process steps used by different manufacturers or at different times."
Do you agree with this statement?
A. I think what they're saying is they are -- essentially they're doing root-cause analysis of how NDMA is being developed, being generated. Do I agree with that statement, "full understanding

Page 45

would require correlation of multiple test results from valsartan API made by different processes with the various process steps"? I think, you know, this is being written by some regulatory people and it's not -- you know, when we looked at the process, it immediately -- you know, something immediately jumped at us and said this is why NDMA is formed.
Q. So would you say that as of August 2018, the FDA was not still a hundred percent sure of how NDMA became present in valsartan API?
MR. NIGH: Form objection.
A. I'm not sure what you mean by "a hundred percent sure," and I don't know whether various key individuals at FDA were looking -- looking at it. You know, if some, you know, QA, quality assurance, person is looking at it, yeah, they couldn't figure it out. If they put it before a very experienced and synthetic chemist, organic chemist, CMC specialist at the FDA, I think they would immediately be able to see the problem.
Q. All right. But this statement which was by Dr. Gottlieb, the head of the FDA, the commissioner of the FDA, he stated: "We are not a hundred percent sure this is the root cause." Correct?

Page 46

A. That's what he says.
Q. Okay. Going down to page 5 at paragraph 1. Okay. Very top of the page.
"Recognizing these risks is based on a deep understanding of the chemistry involved in drug manufacturing and the theoretical risk that an impurity could be a byproduct of an essential step used in the manufacture of an active ingredient."
Do you agree with that statement?
A. I need 30 seconds.
Q. I've got the clock running, don't worry. I-phones are counting.
A. So the key statement here is recognizing these risks is based on deep understanding of chemistry involved in drug manufacturing and theoretical risk that an impurity could be a byproduct of an essential step used in the manufacture of an active ingredient.
And whose responsibility is that? Is that FDA's responsibility or manufacturer's responsibility? In my opinion, as I've stated in my expert report, it is a hundred percent manufacturer's responsibility.
Q. Okay. But would you agree that understanding the risk of nitrosamine formation in

Page 47

valsartan requires an understanding of a theoretical risk that an impurity could be a byproduct of a step used in the manufacture of API?
MR. NIGH: Form objection.
A. I don't understand what they are saying by "theoretical risk." As part of cGMP, your client could have conducted a thorough risk assessment, and -- and that risk assessment should have -- should have conducted, by their lead organic chemist, especially -- especially when they're changing the manufacturing process.
When you -- you know, when you changed, you know, when -- instead of adding sugar, you add artificial sweetener, you know, you're changing -- you're going to change the taste of your cake. You know, and you need to do a risk assessment.
You know, while the taste is going to change, what about its thickness? What about its consistency? What about its weight? That is not theoretical. That is a very serious matter. And, you know, FDA -- you know, on record and off record, I can tell you they have never manufactured a product in their life.
Q. Okay. So again, just trying to go back to my question, and I think you answered --

Page 48

A. I answered it.
Q. You disagree with the FDA that recognizing the risk of NDMA is kind of based on understanding a theoretical risk that an impurity could form. Is that correct?
MR. NIGH: Form objection.
A. So it is -- again, as I've -- I've already answered your question, I think. We should probably move on; but if you want further elaboration, you know, theoretical risk, what FDA is stating here, theoretical risk, a lot of FDA, very experienced chemistry manufacturing control people, they call them CMC experts at FDA, this is not written by their CMC expert; I can tell you that much.
Theoretical risk -- this is not, there's no theory involved in manufacturing. You know, you do a risk assessment.
Q. Dr. Najafi, were you involved in writing this public statement?
MR. NIGH: Form objection.
A. What is -- are you asking me if I wrote this?
Q. Well, you just said that you know for a fact that CMC people at the FDA were not involved in

Page 49

writing this report. So I'm just asking how you know that.
A. Because it doesn't sound like a CMC person.
Q. But you don't know --
A. I can speculate.
Q. I'm sorry, you just said you're speculating that CMC was not involved?
MR. NIGH: Form objection.
A. I am speculating -- it does not sound like a CMC person writing that statement.
Q. But that's your assumption. You don't have any personal knowledge of that?
MR. NIGH: Form objection.
Q. Is that correct?
A. This is based on my experience in the industry for the last 40 years.
Q. But you've never worked at the FDA. Correct?
A. I have never worked for the FDA, but I've worked with the FDA, and I know how they talk as it relates to these matters.
Q. Okay. We'll move on.
I'm going to look at five, paragraph 1, where it states: "Because it was not anticipated

Page 50

that NDMA would occur at these levels in the manufacturing of the valsartan API, manufacturers would not have been testing for it."

Is that correct? I'm just asking if I read that correctly.

A. This is from the same statement because -- the continuation, I think. Because it was not anticipated that NDMA would occur at these levels, these manufacturers -- manufacturer of valsartan API and would not have been testing for it. That's what they say, and I disagree with that statement.

Q. You disagree with the FDA, and the commissioner of the FDA, Scott Gottlieb?

MR. NIGH: Form objection.

A. I do. And I can -- I can further elaborate.

Q. I'm fine. No need. You've answered my question.

A. I respect -- I respect -- yeah.

Q. Thank you.

MS. ROSE: I'm going to move to mark Tab 5. I think that would be Exhibit 4.

(Exhibit Najafi-4, FDA Statement entitled, FDA Statement on the FDA's ongoing

Page 51

investigation into valsartan and ARB class impurities and the agency's steps to address the root causes of the safety issues, dated January 25, 2019, was received and marked for identification.)

MS. ROSE: Thank you.

Q. This document is "FDA's statement on the FDA's ongoing investigation into valsartan and ARB class impurities and the agency steps to address the root causes of the safety issues," and it was issued on January 25, 2019.

Have you seen this document before, Dr. Najafi?

A. I believe so.

Q. Do you know when you first saw this document?

A. I cannot give you exact time and date.

Q. Well, was it after you were retained as an expert in valsartan litigation?

A. I cannot give you exact time and date. It might be before; it might be after.

Q. Did you rely on this document in forming your opinions in connection with this case?

A. If I relied on this, probably it's in my citations.

Q. And if it's not in your citations, does

Page 52

that mean that you did not consider or rely on it in forming your opinions?

A. Yes. I believe I have reviewed it at one point.

Q. All right. In this January 29th press release, the FDA said on page 4, at paragraph 2: "One challenge we faced is that NDMA's properties make it hard to detect in standard laboratory testing the kind of testing results that are reviewed during a surveillance inspection."

Do you agree with the FDA's statement that NDMA's properties make it hard to detect in standard laboratory testing?

A. What page is this again?

Q. Sure. It's right up on the screen in front of you. It's on page 4 at paragraph 2. I'll give you 30 seconds.

A. Oh, no. We need more than 30 seconds. This is --

I have -- okay. Yeah, okay. What's your question?

Q. I just asked if you agreed with the FDA's statement that NDMA's properties make it hard to detect in standard laboratory testing.

MR. NIGH: Form objection.

Page 53

A. I disagree with that statement because prior to this date, in June of 2018 or perhaps even earlier, Novartis, in their very routine GC-FID testing, they saw lots of impurities in your client's API, and they wanted to know what those impurities were.

And they sent it to a contract lab, and they got it -- within a day they knew they had an NDMA in it.

Q. Okay. So you disagree that NDMA's properties make it hard to detect in lab testing?

A. I disagree.

MR. NIGH: Form --

Hold on, Dr. Najafi.

Form objection.

You can answer.

MS. ROSE: I think he answered already.

A. I disagree.

Q. Okay. You just said a couple of things that I want to talk about really quickly. You said that in June of 2018, Novartis discovered NDMA in routine FID, testing?

A. GC-FID testing.

Q. Sorry, apologies for my shorthand.

You also said that maybe earlier they

Page 54

identified NDMA using GC-FID testing.
Do you have any evidence to support the notion that Novartis identified NDMA in valsartan earlier than June 2018?
A. Do you agree that Novartis did find NDMA in their routine GC-FID testing? It's in my report.
Q. Sorry, are you asking me a question or is that your answer?
A. It's the same. It could be an answer and statement. They did find it.
Q. Okay. Is -- does -- stated anywhere in your report that Novartis identified NDMA in valsartan prior to May/June 2018?
A. I don't believe so, but I believe certain individual at your client's manufacturing facility had testified to the fact that they had nitrosation of another sartan as early as 2017.
Q. Okay. Not my question. We can go back to that. Trust me, we can go back to that, but I'm just asking about Novartis.
Do you have any evidence that Novartis identified NDMA in valsartan prior to May/June 2018?
A. No.
Q. And would you agree -- I think you

Page 55

already stated this -- that Novartis didn't identify NDMA in valsartan using GC-FID testing. It wasn't until a contract lab was brought in to test valsartan that NDMA was identified. Correct?
A. So you're making it sound like they had to go to a contract specialized lab to get this done. Novartis has far, far, far more resources in terms of GCMS capability than any contract lab on the planet. The reason why they go to a contract lab, sometimes it's because of internal resources and, you know, resource planning and so forth.
It probably would have taken them longer to actually get it done at their own facility, and it's a lot quicker to send it out to a contract lab. So that's what they did.
GCMS testing is extremely routine, and because Novartis's GC-FID trace was so dirty, was so much full of impurities, Novartis just wanted to know what are all these little tiny impurities. And that's what -- they send it to get a quick response, quick answer.
Q. Okay. But you agree that even with all of Novartis's capabilities, they did not identify NDMA or ask anyone else to identify NDMA in valsartan prior to May/June 2018?

Page 56

MR. NIGH: Form objection.
A. All I'm aware is what has been, you know, shown to me as part of my, you know, various disclosures. I know that Novartis had that at that time and point, and Sovias did the work for them --
(Court Reporter Clarification.)
A. So let me repeat.
You know, Novartis -- Novartis was responsible for identifying NDMA in valsartan. Whether they did it themselves or sent it out to a contract lab, it's immaterial. It's their finding.
Q. Okay. Again, my question was a temporal one.
You agree that neither Novartis, nor any contract lab that they may have partnered with, identified NDMA in valsartan prior to May/June 2018?
A. They might have, but I don't know. I haven't seen any document. They might have.
Q. Did you ask for any documents regarding Novartis's investigation of NDMA prior to May of 2018?
A. No. We were -- I was simply given what the lawyers provided to me.
Q. So the materials that you considered in this case were limited to materials that the lawyers

Page 57

provided to you. Correct?
A. Correct.
Q. Okay. I'm going to change topics quick.
Would you say that you use the same rigor in your work as an expert as you do in your work at your lab at Emery Pharmaceuticals?
A. I do.
Q. Is that true in all the cases in which you serve as an expert?
A. I do my best.
Q. Do you use the same level of rigor and standards in all your expert work?
A. I do my best. I try.
Q. You try to use the same level of rigor in all your cases?
A. Yes.
Q. But you might not always live up to that standard?
A. We're only human and we know what we know, and sometime we don't know what we don't know.
Q. That would be true for pharmaceutical manufacturers as well. Right, Dr. Najafi?
A. That's true. That's true.
Q. When did you start writing the report

Page 58

that you submitted on October 31st, 2022?
A. Probably sometime during summer.
Q. I want to put -- well, you know what? I'll just -- I'll say it.
When you were deposed in February about your first report, you said at the time that you were in the process of creating a second report. Was that accurate at the time?
A. Yes.
Q. So you probably started writing your report prior to February 2022?
A. I can't recall. We have been putting basically lots of communication to the lawyers. You know, I put lots of confidential attorney-client, you know, material together for them, so yeah.
Q. So when would you say you started coming up with the opinions in your October 31st, 2022, report?
A. I cannot put a time and date on it.
Q. But fair to say it was after you were retained as an expert?
A. I started immediately after we were retained, and I've been accumulating opinions as we sort of got documents and reviewing things and so forth.

Page 59

Q. Much of your report concerns actions that you state were taken or not taken by ZHP, who is the manufacturer of valsartan API. Correct?
A. Could you repeat your question?
Q. Oh, sort of a simple point, that your report talks about actions taken or not taken by ZHP. Correct?
A. I also -- you know, it's not only ZHP, you know. It's -- ZHP's API manufacturer. You know, I've also written about the finish dose manufacturers as well.
Q. Okay. Did you speak to anyone from ZHP in forming your opinions?
A. No.
Q. Did you ask to speak to anyone at ZHP?
A. No.
Q. Were you ever told you could not speak to someone from ZHP?
A. No.
Q. And you just said that your report also discusses finish dose manufacturers.
Does that include Novartis?
A. I might have mentioned Novartis, but specifically, finish dose manufacturers that used ZHP's API.

Page 60

Q. Did you speak to anyone from Novartis in forming your opinions in this case?
A. No.
Q. Did you ask to speak to anyone at Novartis?
A. No.
Q. Were you ever told you could not speak to someone from Novartis?
A. No.
Q. Okay. And when you were talking about the finish dose manufacturers for valsartan, would that include Torrent, Teva, Solco, and Princeton?
A. I believe so.
Q. Did you speak with anyone from any of these drug product manufacturers in forming your opinions?
A. No.
Q. Did you ask -- sorry, did you ask to?
A. No.
Q. And were you ever told you could not speak to anyone from these companies in forming your opinion?
A. No.
Q. We've talked a little bit about your report and your list of materials considered. Did

Page 61

you review all of the documents that are included in your report and the list of materials considered?
A. I -- some, I scanned through them. Some, I read through all of it, you know, and yeah, it's been a while.
Q. So you can't say for sure you've looked at every document that's listed on your materials considered?
MR. NIGH: Form objection.
A. I've cited them. I've actually read through parts that I've cited, but I cannot tell you that I've read a hundred percent of the material, of a paper.
Q. Who decided what would be included on your list of materials considered?
MR. NIGH: Form objection.
A. I did.
Q. And how did you make that determination? What documents did you include?
A. Based on documents that were provided to me, and there were a ton of documents that I did not cite.
Q. How did you make the decision of what you cited and what you didn't cite?
A. Material that mattered to the NDMA, I

Page 62

focused on.
Q. How many documents were you provided by the lawyers in total?
A. Do you need an exact number?
Q. Oh, no. An estimate is fine. Dozens? Hundreds? Thousands?
A. More than a hundred, probably less than a thousand.
Q. Do you know how many documents have been produced by the ZHP defendants in connection with this case?
A. No.
Q. Do you know how many documents have been produced by all defendants in the case?
A. No.
Q. Could you say what percentage of the defendants' production you reviewed?
A. No.
Q. Is it fair to say that you don't know if you reviewed the entire universe of documents that have been produced in this case?
A. That's correct.
Q. Did you ask the lawyers to review any specific documents?
A. Did I ask the lawyers -- could you

Page 63

repeat your question.
Q. Sure. Did you ask plaintiffs' lawyers to provide you with any specific documents?
A. Yes, I have.
Q. Which documents?
A. I cannot recall right now.
Q. Any category, you can't give any -- any information about what you may have asked for?
A. No; but I have inquired about, you know, additional documents or additional information regarding various deposition that they were conducting of various individuals. Those -- and in some cases, I've asked to get more detail on some of the deposition, things like that.
Q. Who did you ask when you asked for more information from the plaintiffs' lawyers?
A. Primarily Rosemarie Bogdan and secondarily, Daniel Nigh.
Q. Have you read any of the complaints in this case?
A. Not thoroughly; scanned through them.
Q. And do you know who the plaintiffs are in the case currently at issue?
A. I only know Daniel and Rosemarie; I don't know anybody else.

Page 64

Q. Oh, sorry. I didn't mean the plaintiffs' lawyers. The plaintiffs themselves, who Daniel and Rosemarie represent.
A. No, I do not know any of them.
Q. Have you ever heard of Susan Bain?
A. No.
Q. Have you ever heard of Laura Plunkett?
A. No.
Q. Have you ever heard of Dr. Stephen Hecht?
A. I believe I have, yes.
Q. Who is Dr. Hecht?
A. I think one of the experts on the case.
Q. Have you read the report -- I'm sorry, have you read any report that Dr. Hecht has submitted in the case?
A. No.
Q. Have you communicated with Dr. Hecht at all?
A. No.
Q. Are you basing any of your opinions on information or opinions provided by Dr. Hecht?
A. No.
Q. Are any of Dr. Hecht's opinions relevant to your opinions?

Page 65

A. I don't know what his opinions are, so I can't tell you. I don't know him.
Q. Okay. Do you know who Philip Russ is?
A. No.
Q. Do you know who Laura Craft is?
A. No.
Q. Is it fair to say that if you don't know anyone who I just mentioned who you said you don't know who they are, you are not relying on any opinions they might have provided in this case?
A. Correct.
Q. Is it accurate to say that you're offering opinions in this case as an expert in chemistry?
A. That's correct.
Q. Have you been offered as an expert in any other field?
A. No.
Q. Is it accurate to say that you offer opinions on what was generally known in the field of chemistry regarding the potential for the formation of NDMA or NDEA during the times ZHP was developing and using the zinc chloride and TEA with quenching processes to manufacture valsartan API?
A. Yes.

Page 66

Q. Is it accurate to say that you're offering opinions regarding compliance with cGMPs by manufacturers of generic valsartan API and finish dose products?
A. Yes.
Q. Accurate to say that you're offering opinions as to whether generic finish dose -- sorry, offering opinions as to whether generic finish dose valsartan drugs manufactured using ZHP's API were adulterated?
A. Yes.
Q. And are you offering the opinion that generic valsartan manufactured with ZHP's API is not chemically or pharmaceutically equivalent to the brand-name reference listed drugs Diovan and Exforge?
A. Yes.
Q. Any other general opinions are you offering in this case?
MR. NIGH: Form objection.
A. Whatever I have put in my expert report is the opinion that I've given.
Q. Do you intend to offer opinions regarding causation?
MR. NIGH: Form objection.

Page 67

A. Causation as it relates to what?
Q. Are you offering any opinion about whether nitrosamines are genotoxic or can cause cancer?
A. No.
Q. Are you offering any opinions on the toxicity of nitrosamines?
A. No.
Q. Are you offering any opinions about the level of exposure to nitrosamines that you believe is capable of causing cancer?
A. No.
Q. Are you offering the opinion that a specific patient developed cancer as a result of taking valsartan?
A. No.
Q. And you agree you're not a medical doctor, toxicologist, or epidemiologist. Correct?
A. That's correct.
MS. ROSE: Do you want to take a break right now? It's up to you. We've been going for a bit. I'm happy to keep going. I just wanted to offer you the opportunity.
THE WITNESS: No, let's keep going.
MS. ROSE: Okay, I like your style.

Page 68

THE WITNESS: I have a dinner plan at my mom's tonight, so I want to make it to that.
MS. ROSE: Well, you're three hours earlier than me, at least, so you have a chance. I'm out for dinner, I fear.
Q. All right. Dr. Najafi, who wrote your October 31st, 2022, report?
A. I did.
Q. Did you have assistance from anyone in researching or drafting your report?
MR. SLATER: Work product. Please object. That's work product. They can't ask the question. Come on, guys.
MS. ROSE: I'll rephrase my question.
Q. To be clear, I'm not trying to get any communication you may have with plaintiffs' counsel involved in this case.
MR. SLATER: You can ask who wrote the report or who had input into the report. Under the federal rules, that's work product.
MS. ROSE: Okay. I'm not trying to get into work product at all.
Q. Did you have assistance from anyone, other than lawyers, in researching or drafting your report?

Page 69

A. I have several people here at Emery that I routinely ask for support for research for, you know, various things that they do for me.
Q. All right. So let's go through those people.
Who at Emery Lab assisted you in researching or drafting your report in this case?
A. Dr. Neil Bose, and primarily Dr. Rakesh Jain.
Q. Can you spell that last name?
A. Which one? Bose is B-O-S --
Q. Bose I have. Sorry.
A. Like Bose speaker, and Rakesh is R-A-K-E-S-H, Jain, J-A-I-N, like Nancy.
Q. Okay. Anyone else at Emery Lab?
A. No.
Q. Did anyone else at Emery Lab participate at all in your research or in your report in this case?
A. No.
Q. What specifically did Dr. Neil Bose do in helping you inform your opinions in this case?
A. He's an analytical chemist, Ph.D. analytical chemist.
Q. Okay. And did he perform research?

Page 70

A. He worked for me here in my lab. And he's in charge. He's our chief scientific officer and in charge of our mass GCMS, GC-FID, and in charge of our various LCMS instruments. That's what he does.
Q. Okay. But I'm just asking about his role in you creating your report in this case.
What did he do?
A. Provide me with some of the research activities.
Q. What do you mean by "research activities"?
A. I can't put my finger on it, from time to time I've asked him to, you know, search something or explain something to me or things like that.
Q. Okay. How many hours do you think he spent on this case?
A. Probably five to ten hours.
Q. And did he draft any portions of your report?
A. No.
Q. Did he edit any portions of your report?
MR. NIGH: I'm sorry, I saw your lips,

Page 71

Dr. Najafi, but I am not sure we could actually hear that answer.
MS. ROSE: I didn't hear it.
A. I said, "No." "No." Sorry about that.
Q. Did Dr. Bose review any of the company documents you cite in your report?
A. I believe so.
Q. Do you have an estimate of how many company documents Dr. Bose reviewed?
A. No.
Q. Did he review any draft of your report?
A. No.
Q. Did he decide which documents would be cited in your report?
A. No.
Q. Going to Dr. Rakesh Jain, I assume -- is it safe to assume that that is a he?
A. It's a he.
Q. Great. Thank you. I don't want to assume, so I want to ask.
What was his role in helping you write your report in this case?
A. So Rakesh is a Ph.D. synthetic organic chemist, and I helped -- I asked him to research NDMA from the beginning of time. And he had no

Page 72

access to any of the documents at all.
Q. And did Dr. Jain do all of the research on NDMA that's cited in your report?
A. I believe -- you know, so he put together something for me. I think I've taken -- I've cut and pasted some of his research into my report.
Q. But did you do any independent -- I'm sorry, I didn't mean to cut you off. Were you still speaking?
A. No. I said -- you asked me which -- what I don't recall right now, but I believe I have some of this cut and paste. These are basically literature public information, publicly available NDMAs by things, chemical reactions and things like that.
Q. Did you do any research regarding NDMA aside from what Dr. Jain did?
A. Yes, I did.
Q. Okay. How does your research differ from Dr. Jain's research?
A. Mine was sort of very specific to certain, you know, chemical reactions of NDMA. His was more global. And effectively, I asked him to put a review together for me, almost like a review

Page 73

for publication. You want to publish a review of NDMA and how -- where NDMA, how NDMA is formed, and, you know, were the sources of NDMA. That's what we did.
Q. Okay. So Dr. Jain did the research and you looked at his findings. Is that fair to say?
MR. NIGH: Form objection.
A. Yes.
Q. And you just talked about publication of NDMA. I just wanted to make sure.
You've never published anything regarding the formation of NDMA. Correct?
A. Well, it depends what you consider publication. We -- we submitted a petition to the FDA regarding Zantac and NDMA formation in Zantac on January 2nd, 2020. So that was a publication, I assume, because it was submitted to the FDA and the FDA immediately published it on their website.
Q. Okay. But aside from the citizens petition -- you haven't published --
(Court Reporter Clarification.)
Q. I'm sorry. I'm sorry, Dr. Najafi.
MR. NIGH: Dr. Najafi --
Q. Can I finish my question?
A. I'm sorry.

Page 74

Q. No, no. We're trying the best we can.
Aside from the citizen petition you just mentioned, you haven't published any peer-reviewed literature on the formation of NDMA. Correct?
A. So the petition with the FDA was reviewed and corroborated by FDA. So I considered that as peer reviewed by their analytical chemist and various individuals.
As far as, quote/unquote, peer-review publication, no.
Q. Thanks.
Okay. We just talked a little bit about the ranitidine citizens petition.
You previously testified that you were retained to serve as an expert in litigation regarding ranitidine. Correct?
A. That's correct.
Q. And that litigation involved claims that the recalled drug Zantac was contaminated with NDMA?
MR. NIGH: Form objection.
A. That's incorrect.
Q. What -- how would you describe that litigation?

Page 75

A. So the NDMA in Zantac is not a contamination. NDMA in valsartan is a contamination. Just semantics.
Q. Okay. So to be precise, and I apologize for my lack of precision, the ranitidine litigation involves claims that the drug Zantac included NDMA?
MR. NIGH: Form objection.
A. No.
Q. Let me try one more time.
A. Our -- yeah.
Q. The ranitidine litigation includes -- involves claims that the recalled drug Zantac degrades into NDMA?
A. Correct.
Q. Third time is a charm.
A. Yep.
Q. And you submitted an expert report for the plaintiffs and provided a deposition in that litigation. Correct?
A. Correct.
Q. And am I correct that your work in connection with ranitidine related to litigation that was pending in the United States District Court in the Southern District of Florida?

Page 76

A. I believe so.
Q. Are any of the plaintiffs' lawyers you've interacted with in connection with this suit also involved in the ranitidine litigation?
A. Yes, they are.
Q. Do you know which ones?
A. Rosemarie and Daniel.
Q. And have you talked to Rosemarie and Daniel about both litigations?
A. Yes, I have.
Q. Are you aware that your opinions in the ranitidine litigation were excluded by the Southern District of Florida as unreliable in December of 2022?
MR. NIGH: Form objection.
A. What I'm aware is that all experts were excluded from that litigation.
Q. Okay. And you were one of those experts who was included -- who was excluded?
A. Correct.
Q. Have you ever previously had expert opinions in litigation that were excluded by a court?
A. No.
Q. I'm going to put up Tab -- you know

Page 77

what, I'm going to ask a question first.
Your billing rate, when you submitted your first report in this litigation, was $650 an hour. Is that right?
A. I don't recall. I don't do the billing. It's our accounting team and finance team does that.
Q. Do you know that your billing rate in connection -- it listed -- in your October 31, 2022, report is listed as $720 an hour?
A. I believe so. I'm not -- I have to look at the invoices.
Q. Okay. Did you write that section of your report where you listed your billing rate?
A. I don't recall.
Q. Is $720 an hour the rate you're charging for giving deposition testimony here today?
A. I believe so, but I have to check.
Q. Were you aware that your rate went up for providing expert services in this case between your February '22 deposition and the filing of your October 31st, 2022, report?
A. Yes, I am.
Q. Why did your rate go up?
A. Inflation.

Page 78

Q. How much have you charged plaintiffs to date in connection with this litigation?
A. How much am I charging the plaintiffs today?
Q. No, sorry. I wasn't clear.
Can you give an estimate of how much you have charged plaintiffs total in connection with the valsartan litigation?
A. I would need to look at all of our invoices. I can't give you an estimate.
MS. ROSE: Okay. With that prelude, I'll introduce Tab 8, which would be Exhibit 5.
(Exhibit Najafi-5, Emery Pharma Invoice dated November 18, 2022, was received and marked for identification.)
Please correct me if I'm wrong, Ellen.
COURT REPORTER: You're right. Counsel, when you get to a convenient restroom break time --
MS. ROSE: Oh, sure, yeah. Do you want to stop right now, Ellen?
COURT REPORTER: Whatever is best for you.
MS. ROSE: Sure. We can just take down this exhibit and then we can -- can we take it down

Page 79

before -- if we're not going to get into questioning it?
Okay. Great.
Why don't we do a quick restroom break. I don't need that long.
I don't know how long you need, Dr. Najafi.
Let's go off the record.
THE WITNESS: One minute.
MR. NIGH: I think we'll be about ten to 15 minutes.
THE WITNESS: Okay.
MS. ROSE: Ten to 15?
MR. NIGH: Yes.
THE VIDEOGRAPHER: This ends Media Unit Number 1. We're going off the record.
(A brief recess takes place.)
THE VIDEOGRAPHER: The time is 11:22. This begins Media Unit Number 2. We're back on the record.
BY MS. ROSE:
Q. Dr. Najafi, right before we went off, I had just introduced Exhibit 5, which we can put back up on the screen. You should have that also in your folder if you want to bring it up.

Page 80

A. Okay. I actually -- I hit something and I lost the whole link. Is that in the chat?
MS. ROSE: All right. Let's go off the record and let's figure that out.
THE VIDEOGRAPHER: The time is 11:23, and we're going off the record.
(A brief recess takes place.)
THE VIDEOGRAPHER: The time is 11:24. We're back on the record.
BY MS. ROSE:
Q. Okay, so I will represent to you that these are your invoices which were produced to us by plaintiffs' counsel earlier this week.
A. Right.
Q. Okay. Have you seen --
A. Right.
Q. You produced these invoices to plaintiffs' counsel. Is that correct?
A. I believe my office has.
Q. Okay. And this invoice that is on the first page, which was dated 11/18/2022, that is the most recent invoice that you've issued to plaintiffs?
A. Uh-hum.
Q. Is that a "yes"?

Page 81

A. Yes.
Q. I'm going to assume that you've billed time to this matter since November 18, 2022. Correct?
A. I believe we should have additional invoices --
Q. And have those invoices --
A. -- since November 20th.
Q. Apologies for interrupting. Are you done?
A. I believe there were additional more, you know, work done on -- on the deposition and so forth, so there are a few more invoices.
Q. Have you produced -- I apologize -- have you submitted invoices subsequent to 11/18/22 to plaintiffs' counsel?
A. I do not know. I have to check with our finance team.
Q. Okay. But you think that there are invoices that exist for time billed after November 18, 2022?
A. That's correct.
Q. All right.
MS. ROSE: Defendants would ask that Dr. Najafi produce any invoices between November 18,

Page 82

2022, and the present date that have been prepared.
A. Can you repeat your question.
Q. That was mostly just a statement for counsel. I just wanted to let counsel know that we're requesting any invoices that you have in your possession for time billed on this case after 11/18/2022.
MR. NIGH: I'm not aware that we received any other invoices, but we'll double-check on that.
MS. ROSE: Okay.
Q. Now, Dr. Najafi, we've been through these invoices, and according to my math, you've been paid more than $300,000 in connection with this -- this case based on these invoices.
Would you have a reason to disagree with that?
MR. NIGH: Form objection.
A. I would need to, you know, look at all the invoices and total them up to confirm.
Q. Maybe we'll do that on a break or go off the record later and you can confirm that.
Does that number sound right to you?
MR. NIGH: Just to be clear, I'm not going to ask him to do math on a break. We use

Page 83

breaks for breaks.
You can continue.
Q. Does that number sound right to you?
A. It generally sounds -- if you've done the math and you think it's correct, that's the one it is.
Q. All right. Based on our math, the total amount that you were paid in 2021 in connection with this litigation was over a hundred thousand dollars.
Does that sound right?
MR. NIGH: Form objection.
A. I would need to look at all the invoices. I cannot confirm or deny.
Q. Assuming that my math was right and that you were paid over a hundred thousand dollars in 2021, what percentage of your total income in 2021 would that be generally?
MR. NIGH: Form objection.
A. Probably less than -- less than 5 percent.
Q. And according to my math, based on these invoices, you were paid over a hundred thousand dollars in 2022 for valsartan litigation. So I have the same question on that.

Page 84

Assuming my math is right, what percentage of your income in 2022 would that be?
MR. NIGH: Form objection.
A. Less than I would say -- I would say less than 5 percent. Between 1 to 5 percent.
Q. And how much -- what percentage of your income in 2022 would come from all expert work done in any litigation?
MR. NIGH: Form objection.
A. I cannot tell you it will be 21.35 percent, but it would be probably less than -- in 2021 or 2022?
Q. Both. We can start with 2021, then we'll go to 2022.
A. 2021, probably less than 10 percent.
Q. And 2022?
A. Probably about the same.
Keep in mind, we are a contract research laboratory, by and large. We support companies that come to us for drug development or analytical method development validation, so really we're not -- we're not -- you know, this, what we're doing is -- doesn't constitute a big part of our business.
MS. ROSE: Can we go to PDF page 3.

Page 85

Okay. Great.
Q. If you see here, there's an entry: "Activity consulting chemistry valsartan, Emery Pharma team hours, reviewing and locating documents per counsel's request"?
A. Uh-hum.
Q. What does Emery Pharma team refer to?
A. Refers to my research team that worked for me, and that's -- you know, I primarily mention Dr. Bose and Dr. Jain.
Q. Okay. Anyone else besides Dr. Bose or Dr. Jain included in the Emery Pharma -- I'm sorry, Emery Pharmacy team for which you billed time in this invoice?
A. No, not really.
Q. Okay. You say "not really," but -- I'm asking as an absolute.
Did anyone else do any work on the --
A. I mean, there are some clerical type of activities, but I can't really point to anybody specific. But it's -- it's a team effort here at my company, and I have over 20 people here. And basically what they do for me, I review and, you know, and I basically make my own opinion. I put it together, you know, based on what I think should be

Page 86

done, but I do ask them to do global research on certain things, and they do that for me.
Q. Okay. So you said there's a team of 20 people, so any one of those 20 people, you may have asked to do research in connection with this case?
A. Just Rakesh and Neil would be the main ones.
Q. I'm not trying to belabor the point. I just want to make clear. There were other staff members in Emery Pharma besides Rakesh and Neil who worked on this case for you?
A. I cannot tell you specifically at that point in time on August 16, 2022, you know, out of the time they spent. If they got their receptionist to help us sort out some papers or, you know, organize something, I cannot tell you who it was, but we might have asked somebody to help with certain activities. But by and large, Rakesh and Neil are the primary team members.
Q. And of this 24.5 hours, how much of that time was spent by Dr. Bose and Dr. Jain?
A. I cannot tell you right now. It's hard for me to tell without looking at the -- you know, going back to, you know, August of 2022, and take a look at our, you know, time tracking system and

Page 87

figuring out who did what.
Q. So you do have a time tracking system that would show you who spent how much time on this case on a given day?
MR. NIGH: Form objection.
A. We are a contract research lab, so yes, we do keep track of our time count.
Q. So it would be possible to determine how much of this 24.5 hours was worked by you and how much by other members of your team?
A. Yes, it would be. And this, I consider work product done by my team and I.
Q. Can you say whether the majority of those 24.5 hours that were spent reviewing and locating documents were spent by you versus Dr. Bose and Dr. Jain?
A. I would say majority of it is spent -- is by me. Yes.
Q. So you did the majority of reviewing and locating documents in this case?
A. I cannot tell you exactly. I think I've already answered that question. I'm happy to keep repeating. I think we're just taking time.
Q. I guess I just have one more question. So you have a rate of 650, and you have

Page 88

on this invoice, and this is just as an example, 24.5 hours. You would bill $650 an hour regardless of whether it was you working the time or Dr. Jain or Dr. Bose. Correct?
A. Right.
MS. ROSE: Can we go to PDF page 1.
Q. 11/18 invoice. I just had a clarification, sorry.
On the last invoice, it says: "Conference call with Emery Pharma and counsel on October 27, 2022," and this says "quantity, 4."
Would that be -- just looking at this, would you think that that was four separate conference calls on one day or four hours, one four-hour conference call, or is it an hour conference call with four different people on it?
A. I'll tell you what it was at this time. It could be four hours' conference call; it could be two people, two hours' conference call.
Q. Okay.
A. We would have to get our accountants involved in this.
Q. Got it.
MS. ROSE: All right. We can take this tab down for now.

Page 89

Q. Dr. Najafi, your report discusses Form 483 reports issued by the FDA. Correct?
A. Two -- repeat your question.
Q. Sure. Your report in this case discusses Form 483 reports issued by the FDA. Is that correct?
A. Form 483 issued by the FDA to who?
Q. To ZHP.
A. Okay.
Q. I'm just confirming you discussed the term "Form 483 reports" in your report in this case.
A. Yes, I have.
Q. Could you just briefly explain what is a 483 report?
A. Form 483 is typically given to -- you know, there are basically degrees -- there are findings that FDA, during the inspection of the facility, discovers. If you're not compliant for certain activities, cGMP, typically, you know, various CFR-related activities and if they're not compliant, they get a Form 483 issued to them.
It's a citation. And you need to, you know, correct things, you know, within a certain period as you agree with the inspector and so forth.
Q. Would you say that a Form 483 report is

Page 90

evidence of a cGMP violation?
A. Yes, it could be.
Q. All right. I think we discussed.
So your role at Emery Pharma, you're the founder and chairman currently. Correct?
A. That's correct.
Q. And you've been in that role from 2011 to the present?
A. That's correct.
Q. I think you've described Emery Pharma as a contract testing lab a couple of times. Is that correct?
A. Contract research lab.
Q. Okay. But Emery Pharma --
A. There's a distinction.
Q. Oh, apologies. I didn't mean to speak over you.
MS. ROSE: Did you get that, Ellen?
COURT REPORTER: I don't believe I did.
A. I said it's a contract research lab and not a contract testing lab.
Q. You testified at your last deposition that Emery does not sell or manufacture any drug product but you do release them.
Does that sound accurate?

Page 91

A. That's correct.
Q. What do you mean by "release"?
A. Release is a term that's used as it relates to a manufacturing product, a GMP. Typically it's called GMP release. So when you manufacture a product, you undertake certain activities as it relates to HPLC, LCMS. You know, you could do melting point, boiling point, you know, various activities that confirms that the identity of your drug, the purity of your drug, and various aspects that's set by the manufacturer, by the producer.
And then once you -- they meet those criterias, then you can say we're not officially releasing this product, releasing it into the market. So it's a release to the market.
Q. It's the manufacturer of the drug that releases it into the market. Correct?
A. So the manufacturer could do, you know, official releasing or a contract manufacturer could do that or a CRO like us could do that.
Q. So you have released -- when you have released a drug product onto the market, is there a form you fill out? How does one release a drug product onto the market? Do you have to file

Page 92

something with the FDA?
A. So what -- you know, in our instance, what we do is we go through the series of testing that clients would ask us to do, and then we give the client a certificate of analysis based on the criteria that they have specified.
And then we say: We are now officially giving you the certificate of analysis, that you can release it. Now the manufacturer does whatever they want to do, they need to do additional work, and that's terminology of releasing.
Q. Okay. So you release a certificate of analysis to the manufacturer?
A. Right.
Q. Okay. Perfect.
You testified at your last deposition that Emery received a Form 483 in 2021.
Do you recall that?
A. Yes, I do.
Q. And you testified that the Form 483 was about data backup that did not comply with the regs.
Do you remember that?
A. Yes, I do.
Q. Okay. And you also said it was a risk management issue and their question was: "What

Page 93

happens if there's an earthquake and we lose all the data?"
Is that an accurate assessment of the 483 report?
A. That's correct.
Q. Okay.
MS. ROSE: I want to put up Tab 11.
(Exhibit Najafi-6, Form 483 issued to Emery Pharma, dated April 9, 2021, was received and marked for identification.)
MS. ROSE: This should be available for you as well.
COURT REPORTER: This is 6?
MS. ROSE: Thank you. This is 6.
Q. Dr. Najafi, this is the form -- Form 483 issued to Emery Pharma on April 9, 2021. Correct?
A. I need 30 seconds.
Q. Okay.
A. I'm loading it up on my second monitor.
Okay. It is.
Q. And this Form 483 states that it is issued to you specifically as CEO. Correct?
A. Yes.
Q. And the type of establishment inspected

Page 94

is listed as a control testing laboratory?
A. Right.
Q. And do you agree with that designation?
A. That's their designation. It's not ours.
Q. And below, the Form 483 lists three observations labeled A, B, and C. And it's --
A. Correct.
Q. And -- okay. Hold on. I'm sorry.
So for A, the observation A, it is the first observation, states that it relates to the FDA's -- I'm sorry -- relates to the FDA's review of what appears to be a standard operating procedure. Is that right?
A. Where are you reading? "A, the following was noted during a" -- okay. It was -- not. Yeah, yeah, so what's -- what's the question?
Q. Okay. So there are two subobservations under observation A, and they relate to an inspection conducted on April 8, 2021. Correct?
A. Right.
Q. Okay. All right. And the first subobservation says that Emery failed to follow Section 6.4.2 of the SOP given that users of, redacted, utilized for, redacted, did not have

Page 95

unique usernames and passwords. Correct?
A. Yes.
Q. Is it safe to assume you know what's underneath these redactions?
A. I have the original, you know, file.
Q. Is it your understanding -- no, go ahead.
A. Yes, so these are equipment, in all likelihood. I don't have access to the original 483, but these are equipment. And it's really referring to that, you know, equipment needs to have unique username/password for every -- every -- every chemist who operates these instruments.
Q. Okay. So the FDA found that Emery employees were using the same username and password to access the computer system?
A. That's correct.
Q. Okay. And that was in -- contrary to the SOP for the lab?
A. That's contrary to basically -- there was -- I believe there was no SOP. The equipment could not have the username/password. It was not possible for the equipment to have that, and we had actually managed that equipment without having that unique username/password.

Page 96

Since then, we've upgraded the password, upgraded the instruments with additional software to be able -- enable us to do unique username/password for every individual.
Q. Okay. But at the time --
A. They -- yeah.
Q. -- at the time of the inspection that was mentioned, Emery Lab was not following the SOP that required unique username and passwords for each chemist. Correct?
A. That's correct.
Q. And is not following an SOP a cGMP violation, in your opinion?
A. Yes, it is. That's why we have this 483.
Q. Okay. So it's your understanding that this 483 is showing that your lab failed to follow a cGMP?
A. This 483 is indicating that we had to upgrade our software in order to be able to operate that particular instrument. In fact, FDA gave us an additional year and a half to actually do that. So we -- because they needed this particular drug release and there are not too many contract labs that can do the work, they basically said, Please

Page 97

continue, but please remedy this problem and we're going to give you, you know, a year to do it.
And then we couldn't do it within a year. We told them we needed -- we need more time, and they gave us more time. And ultimately, I think we ended up getting it done, I think, just a few months ago.
Q. Okay. But my question was a little bit different. I appreciate the clarification.
My question was by issuing this 483, the FDA was saying that as of April 8th, 2021, you were not following cGMP. I understand that you have taken steps to remedy that, but that, by virtue of this 483 inspection, that is what the FDA found?
MR. NIGH: Form objection.
A. I think I answered your question. That is a finding by FDA. It's a violation of cGMP rules, and they gave us, you know, about a year to comply with it. And we needed more time. They gave us more time, and we finally were able to make it happen.
Q. Okay. So the second --
A. And the following -- and the following violations are also -- Item Number 2, it's also related to that. They wanted to make sure that we

Page 98

have backup, we have audit trail. If somebody would delete a file, there would be an audit trail, and all of those were part of the same thing.

Q. Right. I was just going to get to number two. So number two says that the SOP was not followed as raw data and audit trail files from software could be modified and deleted.

A. Correct.

Q. So someone in the lab could delete raw data and audit trails without there being a record of it?

A. That's correct.

Q. And that was also a cGMP violation as of April 2021?

A. That is correct. And they provided us more time to remedy those issues, which we have remedied.

Q. Appreciate that.

So the next sentence down says: "The director of quality has administrative abilities to modify and delete data files on all computer systems in the laboratory."

Is that also a cGMP violation?

A. That is also a cGMP violation. So we actually remedied that immediately so that he

Page 99

wouldn't -- he wouldn't have access to it.

Q. But prior to remedying it, the director of quality could just delete data files on your computer system or delete your testing information without it being recorded?

A. That's correct.

Q. And observation B says: "Your firm lacks an approved release testing procedure." And it says that you released identification material results -- let me see. Hold on. Released identification material -- material results, and then it says from certain dates by redacted.

Just trying to understand, is that redacted, is that also like a computer system?

A. These are -- you know, you have to have a procedure for, you know, essentially a release testing. We have procedure for testing the material, but they need to have a procedure for procedure. So basically they said you need to have one. We did have one on draft, and I think we, as I recall, we basically gave it to them while -- during their, you know, inspection.

Q. Okay.

A. And that was remedied.

Q. Before it was remedied, was the failure

Page 100

to have an approved testing procedure a deviation from cGMP?

A. Yes, it is.

Q. And this says that you did not have an approved testing procedure from August of 2019 to February of 2021. Did you alert any of your customers that you released test results during that time period without an approved procedure?

A. Yes, we did.

Q. And did you tell your customers that the results that you released during that time were not reliable?

A. The results that we provided them was reliable. FDA, actually, the inspectors found no problem with the results with our data, with our interpretation, with our, you know, certificates of analysis whatsoever. And so to that end, we had no problem.

We shared our 483 with customers that we had release data, and a couple of them came for an inspection of our facility and, you know, so they -- we've had inspections from our customers, our clients, and all of them are continuing working with us because the work we've done has been extremely good.

Page 101

And it's really -- the issue is around procedure that need to be in place or, you know, basically release testing. There should be a release testing procedure, which is debatable whether really we needed to have one, but FDA thought we should have one, so we put one in place. We had one in draft form, and then the data issue and the software issue, you know, our customers basically said, well, you know, it can be managed, that username/password with some logbook, because just the computer couldn't manage it.

So we were managing it with logbook until we were able to actually find the software now. Everything has been resolved, and we lost no customers over this. Period.

Q. Okay. You just said a second ago that it was questionable whether you had to have an approved release testing procedure, but the FDA said you did. So would you agree that the FDA saying that you need something doesn't necessarily make it true?

MR. NIGH: Form objection.

A. Would you sort of rephrase your question?

Q. Sure. I'm just trying to get at what

Page 102

you just said.
You said it's questionable whether you needed an approved testing procedure even though you were cited by the FDA as -- for a cGMP violation for not having one. So I'm just trying to get at if you disagree that the FDA giving you a Form 483 saying you needed a release testing procedure, it's your position that the FDA overstated what you needed to do?
MR. NIGH: Form objection.
A. Sometimes you can negotiate certain procedures and SOPs, and if you can make a good reason why one is not necessary because there are other procedures that effectively manage that activity, they would agree. By and large, you know, a lot of this is common sense, and, you know, if they see that we're doing some clerical activity that's unnecessary, they might say, let's forget about that.
So it is negotiable to some extent, but in this case, I think they managed to convince my team that we need one, and we put one -- we -- I think we already -- from what I recall, we already had one in draft form, and we effectively issued it on -- when they were visiting here.

Page 103

Q. Okay. And on Observation C, it says: "Your firm lacks an approved procedure defining roles for computer systems."
And that's also a cGMP violation?
A. Yeah, you know, you could say it is a cGMP violation. What really this refers to is it's like when you give permission to an operator to use a computer, you want them -- you want to limit their access to certain part of the computer or certain folders in the computer. And that's referring to limiting access to certain folders. So it's really related to issue number 1 on -- you know, basically username/password and limiting access.
So it is, you know, a cGMP violation, but it was something that they felt we should focus on, and we ended up focusing on it and it took us nearly two years to make it happen.
Q. In light of this document, is it fair to say that the 483 report covered more than just what happens if there's an earthquake and you lose data?
A. Pardon me?
Q. Is it fair to say that this 483 report covers more than what happens if there's an earthquake and you lose data?

Page 104

A. It is -- it includes that because you may also -- you know, loss of data is a big -- big problem as well. So, you know, we're in an earthquake zone and a flood zone and you name it, and they want to essentially weekly backup or daily backup into the cloud, which we instituted.
Q. But nothing on this document refers to having daily backup, weekly backup, or earthquake-related prevention of data loss?
MR. NIGH: Form objection.
A. No.
Q. Okay. Has --
A. So --
Q. -- the FDA issued anything to Emery Pharma since your last deposition confirming that all of these observations have been remedied?
A. Would you rephrase your question.
Q. Sure. Has the FDA issued anything to you in terms of a document confirming that these observations have all been remedied?
A. So they don't really typically issue any documents, so we basically tell them it's been remedied, and they take our word for it. And this will come up during their next inspection. So during their next inspection, they'll be here and

Page 105

they'll be looking at these items and testing it to make sure that we've actually complied.
Q. When is your next -- next inspection scheduled?
A. It could be today. Nobody knows; it's a surprise audit.
Q. All right. Changing gears.
Prior to starting Emery Pharma, you were the founder, chairman, and CEO of NovaBay Pharmaceuticals. Right?
A. That's correct.
Q. And you took NovaBay public?
A. That's correct.
Q. Do you continue to own any shares in NovaBay?
A. No.
Q. And NovaBay is a medical device manufacturer?
A. NovaBay, when I was there, we were developing drugs for urology, for impetigo, a skin infection, for a number of things. Right now they're doing a lot of different things. I'm not really keeping track of them. I'm no longer there.
Q. When you were there, did NovaBay manufacture any pharmaceutical API?

Page 106

A. Yes, we did.
Q. Which ones?
A. We already discussed that. NVC-422, and it was contracted out to Carbogen.
Q. Got it. Thank you for clarifying.
Outside of any testing related to valsartan, have you personally worked with the solvent DMF in your career?
A. Yes, I have.
Q. In what context?
A. I -- so in graduate school, you know, working on my Ph.D., I was doing -- looking -- synthesizing molecule, and in the course of synthesis of a molecule, you try different solvents. You want to potentially improve your synthesis. And DMF was one of my solvents of choice, although I tried to avoid it as much as I could because -- it's a good solvent for the chemical reaction, but it actually causes testicular cancer, so I was trying to stay away from it as much as I could.
Q. When did you come to the opinion that DMF causes testicular cancer?
A. It's in the literature, the --
(Court Reporter Clarification.)
A. It's a teratogen. It causes -- you

Page 107

know, you lose your ability to have a child.
Q. You're saying DMF causes infertility?
A. Yes.
Q. And is that when you're exposed to it in a lab setting?
A. No, I was never exposed to it. You asked me if I used DMF. I said it's a great solvent. I used it in my chemistry, but I try to avoid it as much as I could. But it's one of those necessary evil solvents that you need to use to get the job done.
Q. I'm just trying to be clear. So are you saying that when DMF is used in creating a drug substance, that drug substance can cause testicular cancer?
A. You asked me about DMF. I told you about DMF. DMF is dimethylformamide. It has toxicity, and, you know, those make the poison. So it's really a matter of how much exposure you have to DMF. But DMF is not a very safe solvent; that's the bottom line. I used it.
Q. When is the last time you used DMF?
A. You want time and date?
Q. No.
A. I would say between -- I used it off

Page 108

and on in 1985, '86, '87, '88, '89. I used it when I worked at a chemical company, at a pharmaceutical company, you know. So it's one of those solvents that a lot of chemists go to because it's -- it has an ability to dissolve organic, and also it has an ability to dissolve some water-soluble molecules, so it's a good solvent.
Q. Does your lab, Emery Pharmaceuticals, do they use DMF as a solvent?
A. I cannot recall offhand, but we do have DMF here on our facility. I'm not sure when we used it or if we use it.
Q. Why would you have the DMF if you don't use it?
A. We have a lot of solvents that we don't use.
Q. So you can't say if you or anyone at Emery Pharma has used DMF as a solvent since 2011?
A. No, I cannot.
Q. And outside of any work related to valsartan, have you or anyone at your lab performed reactions using DMF as a solvent and observed DMF degrading into dimethylamine?
A. Kindly repeat your question --
Q. Sure.

Page 109

A. -- or clarify it.
Q. Outside of any work related to valsartan, have you or your labs performed reactions using DMF as a solvent and observed the degradation of DMF into dimethylamine?
A. So like -- as I mentioned to you before, I've used DMF, you know, many, many, many times, and I have not, you know, made an observation that it causes degradation into dimethylamine.
Q. And outside of any testing related to valsartan, have you performed any testing using DMF as a solvent and observed the formation of NDMA?
A. I have not.
Q. In times when you've used DMF as a solvent, have you always tested for NDMA as a result of the reaction?
A. I cannot recall. DMF, on its own, may not -- doesn't generate NDMA. DMF, you know, has impurities. Even fresh brand-new DMF that you buy from, say, some Sigma-Aldrich probably will contain some dimethylamine.
And as you heat it, as you expose it to acid or base, you generate more dimethylamine. But if I put it in hundred different reaction, if you -- there's no expectation of NDMA. You have

Page 110

expectation of NDMA when you use sodium nitrite. So if you use sodium nitrite, then you have expectation of NDMA.

Q. Okay. So when using DMF as a solvent outside the presence of sodium nitrite, there's no reason to test for NDMA?

A. When using DMF without the use of sodium nitrite, you do not need to test for NDMA, correct.

Q. But you just said a second ago that NDMA -- I'm sorry, I misspoke. Too many acronyms.

You just said a second ago that DMF that you purchased from Sigma-Aldrich could contain some dimethylamine. So there's no need --

A. Yes.

Q. -- to test for NDMA, even though there might be some dimethylamine in the DMF?

A. Right. You just have dimethylamine in DMF. There is no -- yeah.

Q. Is it your opinion that the DMF used by ZHP contained dimethylamine when it was purchased in its pure form before it was used in a reaction?

A. I have not tested the DMF that ZHP used in their product, but I would rely on my expert opinion that there will be perhaps nanogram or

Page 111

microgram quantities of dimethylamine already present in DMF.

And I want to qualify that. As your client uses DMF, they're exposing DMF to heat, acid, and base. All three will further the amount of dimethylamine.

Q. All right. We'll get there talking more about that process. I just want to really be clear on what your opinion is.

So it is not your opinion that a pharmaceutical manufacturer that uses DMF in a manufacturing process is required to test for NDMA unless its process also involves sodium nitrite?

MR. NIGH: Form objection.

A. So my opinion has been that in order for you to have an NDMA form, you need sodium nitrite, or in the case of Zantac, you need to have a nitrite or nitrate -- or nitro group on a molecule. So, you know, it's really a function of NO2, you know, sodium nitrite, those are chemicals that one as part of your risk assessment, you know, in a -- you know, in a good cGMP operation, you do the risk assessment and you effectively say, yeah, we should be expecting NDMA.

Q. All right. In your opinion, should

Page 112

pharmaceutical manufacturers who use DMF as a solvent test for NDMA -- who used test -- let me strike the whole thing.

Should pharmaceutical manufacturers who use DMF as a solvent test for NDEA, period, full stop?

MR. NIGH: Form objection.

A. If the pharmaceutical manufacturer is using only DMF and there is nitro, NO2, there's no sodium nitrite involved, and they need to do a global risk assessment on every step of their synthesis and then say, does it make sense to test for NDMA or not.

Q. So it's a subjective analysis as to whether NDMA --

(Court Reporter Clarification.)

Q. Sorry. I was -- are you saying it's a subjective analysis as to whether testing for NDMA is required when using DMF?

MR. NIGH: Form objection.

A. Case-by-case basis.

Q. Outside of any testing related to valsartan, have you personally worked with triethylamine, or TEA?

A. I have personally worked with

Page 113

triethylamine, again, back in graduate school and back when I worked at a pharmaceutical company in Philadelphia and back where I worked at a chemical company. So triethylamine is the molecule I'm familiar with.

Q. And have you -- outside of your work related to valsartan, have you ever performed reactions using TEA and observed the formation of NDEA?

A. Triethylamine just doesn't form NDEA --

(Court Reporter Clarification.)

A. Prior to -- yeah, I said triethylamine does not readily form NDEA. You need the nitrosating agent, which is that NO+. The NO+ comes from sodium nitrite.

Q. Okay. So it's -- is it your opinion that a pharmaceutical manufacturer using triethylamine needs to test for NDEA if sodium nitrite is not involved in the process in which the TEA is being used?

A. So in the -- when you're using triethylamine, trimethylamine, dimethylamine, any -- I'm sorry if I'm going too fast for you -- any of these reagents in the presence of sodium nitrite is very prone to formation of nitrosamine. This

Page 114

chemistry goes back to 1970s, late seventies.
In fact, when I was in undergraduate as a chemist, chemistry undergraduate, there was huge publicity on, you know, sodium nitrite being added to cold cuts and being added to meats, you know, in the delis of different grocery stores. And it resulted in people saying, you know, you got to have a label on these meats and all that.
So sodium nitrite is a very well-known sort of an actor and very well known in -- both in food industry and in pharmaceutical industry. And in the presence of amines, dimethylamine, triethylamine, it forms nitrosamine. 50 years. 50 years.
Q. All right. We're going to get back to that. I just want to close out this -- this train of thought.
So you just mentioned that NDEA is formed when a nitrosonium ion reacts with triethylamine. Is that correct?
A. That's correct.
Q. Can a nitrosonium ion react directly with triethylamine to create NDEA, or are there intervening steps?
(Court Reporter Clarification.)

Page 115

MS. ROSE: No problem. And I think maybe we'll provide you with a list of these scientific terms to help you with spelling.
Q. You said earlier that NDEA is formed when a nitrosonium ion reacts with triethylamine. Is that correct?
A. Correct.
Q. And you said that that's been well known since the seventies?
A. That's correct.
Q. Okay. I'm going to take a step back to talk about a different subject, and then we're going to come back and we're going to talk about DMF and TEA and all this fun stuff.
So let's look at your report which is Tab 7. I think this will be Exhibit 7, Ellen; is that right?
(Exhibit Najafi-7, Expert Report of Ramin (Ron) Najafi, Ph.D. dated October 31, 2022, was received and marked for identification.)
MS. ROSE: Exhibit 7, is that where we are?
THE VIDEOGRAPHER: Yes.
Q. All right. On page 12 of your report, which should be --

Page 116

MS. ROSE: 14 of the PDF. There you go. Perfect. Thank you. Hold on. Is that where we are?
THE WITNESS: Page 14.
Q. Sorry. It's page 14.
A. Okay, I'm on page 14.
Q. Hold on. I'm just making sure I have the right page. Give me one second.
A. Not the same as mine.
Q. Okay. It's on page 12 of the report, not page 14. And it is the last sentence of the first paragraph. And it says: "Valsartan with NDMA and/or NDEA would constitute an adulterated drug."
Do you see that?
A. Adulterated, okay. I lost -- lost my other monitor. Hang on one second.
Q. Are you having --
MS. ROSE: Why don't we go off the record.
THE VIDEOGRAPHER: The time is 12:24. This ends Media Unit 2. We're going off the record.
(A brief recess takes place.)
THE VIDEOGRAPHER: The time is 12:44. This begins Media Unit Number 3. We're back on the record.

Page 117

BY MS. ROSE:
Q. Dr. Najafi, we've now had two breaks during the deposition. I just wanted to ask, did you speak with anyone during those breaks?
A. During the breakout, I spoke to Rosemarie and Daniel.
Q. During both breaks?
A. You know, when we went to break, yeah.
Q. Okay. So we've had two breaks. So during each break, you spoke to Rosemarie and Daniel?
A. Yes.
Q. And did you review any documents during either break?
A. No.
Q. Thank you.
All right. I believe we just introduced Exhibit 7, which is your report, and we were looking at page 12, which talks about your opinion that valsartan with NDMA or NDEA would constitute an adulterated drug.
You looked at that already?
A. This is page -- which page was that?
Q. Page -- sorry. I thought we were taking a break so you could pull up the document.

Page 118

Do you have it pulled up?
A. No, I have the document. This is what section? What page?
Q. You are on page 12 of your report, the last sentence in the first paragraph.
A. Got it.
Q. Line 4. And it's on the screen as well.
A. Well, I'm looking at my -- the report that you have uploaded. It's -- it's not the same.
Q. Okay.
A. Are you looking at my expert report?
Q. I'm looking at your expert report. We can go off again and we can sort it out. Sorry. I thought we sorted this out during the last break.
MR. NIGH: I think the discrepancy is it's page 14 on the PDF number, numbered page 12 on the --
MS. ROSE: Just look at the numbered pages every time I talk about the report. Right at the bottom of the report on each page, there's a number.
A. Right.
Q. Look at your page numbers, not the PDF.
A. I'm looking at page 12 of my report.

Page 119

Q. Got it.
Do you see the sentence that's in highlight?
A. No.
MS. ROSE: Okay. Let's go off again. Let me go off the record again.
THE VIDEOGRAPHER: The time is 12:46. We're going off the record.
(A brief recess takes place.)
THE VIDEOGRAPHER: The time is 12:48. We're back on the record.
BY MS. ROSE:
Q. All right. I think we've sorted out that we're talking about the fourth line down on page 12, valsartan and NDMA?
A. Yeah.
Q. Okay. Great.
Adulterations is a finding made by the FDA. Correct?
A. That's correct.
Q. Is a product adulterated even if the FDA has not issued a finding that it's adulterated?
MR. NIGH: Form objection.
A. The definition of adulterated to me is if there's a problem with the purity and identity of

Page 120

the drug, then it's considered adulterated. FDA has certainly, you know -- you know, has written about it in their various, you know, guidances and so forth, but it's really that, you know, if there's an impurity. It's like milk can be adulterated. Foods can be adulterated. It means it's not -- there's something in there that shouldn't be there.
Q. Who determines if a product is adulterated?
A. FDA determines it, the manufacturer can determine it, but, you know, it's not, you know, exclusive to any agency.
Q. Did the FDA make a finding that generic valsartan was adulterated prior to the summer of 2018?
MR. NIGH: Form objection.
A. I do not recall that they have -- they have had any findings regarding adulteration of the drug prior to the summer of 2018.
Q. But sitting here, you have no reason to believe that they did?
A. No.
Q. Is it your opinion that generic valsartan is adulterated because the ZHP's API was not manufactured in conformance with cGMP?

Page 121

A. I believe because -- yes, that's correct. It was adulterated primarily because your client did not follow cGMP, very important cGMP requirements as it relates to purity, identity of their manufactured product.
Q. Does any cGMP violation by a drug substance manufacturer render all drugs made with that drug substance adulterated, in your opinion?
A. No.
Q. How do you know if a cGMP violation rises to the level of rendering a product adulterated?
A. You know, if they find impurity in the drug that's not supposed to be in it, especially if it's genotoxic, then you could label it as adulterated.
Q. Okay. So if an impurity is found in the drug, then it is adulterated.
Is that what your testimony is?
MR. NIGH: Form objection.
A. If there isn't -- if there is an impurity that is not part of what impurities supposed to have in the drug, and if -- specifically if it's genotoxic, if it's one of those cohorts of concerns, then, yes, it's designated as adulterated.

Page 122

Q. So is it your opinion that any drug product that includes an impurity listed in the cohort of concern renders it adulterated?
MR. NIGH: Form objection.
Q. Sorry, let me restate the question because I think I was confusing.
Is it your opinion that any drug product that contains an impurity that's listed within the cohort of concern is adulterated?
MR. NIGH: Form objection.
A. Only if it's uncontrolled. So by that, you know, there are genotoxic molecules that are used, for example, for cancer chemotherapy, you know, so -- and there are maybe even more genotoxic, but you need to know what's in it. If you have no clue and then you have a genotoxic pop up in your compound, then it's adulterated.
But let's, for example, say, you know, ZHP knew that NDMA is being formed and ZHP basically said, we're going to keep the NDMA to 10 nanogram per pill -- that's our top limit for this genotoxic compound -- and FDA accepts it, then it's no longer adulterated.
Do you follow?
Q. I'm a little unclear.

Page 123

You're saying if the FDA says that the amount of genotoxic impurity in your -- in a manufacturer's drug substance is okay, then it is not adulterated.
A. Exactly, so if -- sorry for me quickly responding.
Okay. So what I said was if the genotoxic -- let's say valsartan says, we cannot manufacture valsartan without having some NDMA in it and they put some control limits to it and say, okay, maximum we're going to have is 20 nanogram per pill and FDA okays it, then that becomes part of your impurity profile that you need to then monitor and, you know, continuously keep track of and it's no longer adulterated.
Q. Would you say that a drug substance or drug product that includes impurities below the 0.1 USP monograph standard is adulterated if the manufacturer does not specifically confirm none of those impurities are genotoxic?
A. You're asking my opinion on -- could you rephrase your question.
Q. I don't know that I can --
MS. ROSE: Can you read it back, Ellen.
(Testimony read back.)

Page 124

A. Very good question, you know.
Q. Thank you, Doctor.
A. Yeah, I think, if the manufacturer, you know, sees the impurity -- let's say, less than .1 percent, let's say .05 percent -- identifies it, and says, this is not one of the cohorts of concerns, and then reports it to the FDA and comes up with some rationale as to why this impurity is harmless, yes, it can sustain the drug.
Q. That's different from my question, which was, my question was are drug substance and drug manufacturers required, in your opinion, to test all impurities that are under the 0.1 percent USP standard and determine if they are genotoxic in order to ensure the drug is not adulterated?
MR. NIGH: Form objection.
A. I think it's the responsibility of the manufacturer to do a thorough due diligence into every impurity that's produced with .1 percent, .05 percent, .01 percent. As long as they can see a peak on the chromatogram and as long as it's a nice baseline to baseline, you know, sort of a peak, it doesn't matter how small it is. You cannot dismiss those peaks as -- you know, I think your client called them ghost peaks or noise, you know.

Page 125

So they need to monitor those impurities, and then they need to do what Novartis did, which is -- Novartis isn't even manufacturing the product. They bought -- they just were looking to buy some, you know, valsartan drug substance from your client, and they just ran a GC-FID.
And I saw the chromatogram; it was awful, you know, and it was full of impurities. And they basically said, we want to -- we want to do the right thing. We want to see what these impurities are. There's nothing wrong with that.
And today, Nina, you know, with the presence of GCMS can actually train you in about no more than an hour how to actually run those, you know, GCMSs. It's so simple; it's point and click.
Q. Okay. I think we've gone a little far afield of the question when we're talking about my training to run GCMS.
A. I was just trying to kind of --
Q. I appreciate --
A. -- give you a little bit of an education.
Q. I appreciate your confidence in me and my scientific skills.
As of 2013, was there any FDA

Page 126

regulation or guidance that required drug substance manufacturers to test for impurities under the 0 -- sorry, 1. -- sorry, .1 -- let me start that again.

As of 2013, was there any FDA regulation or guidance that required drug substance manufacturers to test for impurities under the .10 level?

A. There were -- I think, 2015, there was a draft guidance.

Q. My question was related to 2013, as of 2013.

A. As of 2013, there were -- there were Q3, Q3A. There were a bunch of guidances, and I think Q3A, Q3B that pointed to genotoxic compounds and testing for them. Genotoxic toxins have been a concern since, you know, I was an undergraduate. And nobody wants them in their drug, and there -- you want to make sure you have the proper testing methodology, especially if you see them in your chromatogram. You got to identify and you got to justify it. You know, if -- okay, maybe I'm talking too much.

Q. I understand -- you answered my question, and you raised another question that I have.

Page 127

You just referenced what I believe is ICH Q3. ICH Q3 doesn't appear anywhere in your report or on your reliance -- your list of materials considered.

MR. NIGH: Form objection.

Q. Is that -- apologies. I'm sorry, I didn't finish my question. It doesn't appear anywhere in your report or on your list of materials considered, and earlier you said you didn't consider anything in forming your opinions that wasn't included with your report.

Did you consider Q3?

MR. NIGH: Form objection.

A. Q3, Q3AB are mentioned in the -- in the M7. They're predecessors, you know, to M7.

Q. Got it.

So it's your position that as of 2013, pharmaceutical manufacturers were required to test impurities under the USP .10 percent standard pursuant to ICH Q3. Is that right?

A. It is my opinion that from the beginning of time, as long as people have had access to gas chromatography, if you see a peak, as little as it can be, you need to try to -- you need to make an attempt to identify it.

Page 128

Q. You need to make an attempt to identify any impurity of -- at any level even if it's under the USP 0.1 standard. Is that correct?

A. Absolutely -- absolutely.

Q. And you say that is set forth in ICH Q3?

A. ICH -- you know, it's Q3A, Q3B, M7, all of those.

Q. You're saying those standards say test for any impurity at any level?

A. Those -- you need to make sure your product is free of genotoxic compounds, and genotoxic compounds could be as low as .00001 percent, Nina.

Q. I see what you're saying, but what I'm trying to get at is are you saying that all manufacturers of all drug substances have to test every impurity, even those that are below the USP standard for 0.1 percent for genotoxic impurities? All manufacturers?

MR. NIGH: Form objection.

A. All manufacturers must look at -- specifically when you're doing residual solvent analysis, you're not going to have a thousand different little peaks. You're going to have maybe

Page 129

20 little impurities, just like Novartis.

Yeah, they have -- they have to do it; otherwise, they're in the wrong business. Do you want to take genotoxic impurity, Nina, for, you know, rest of your life, especially if you're on a chronic drug that you're taking every day? I know I don't.

Q. So what is the point of a USP 0.10 percent standard for testing for impurities if all manufacturers are required to test all impurities to make sure that they're not genotoxic no matter what the level?

A. You need to report -- any impurities that are, you know, .1 percent, then .05 percent, you need to identify them. You need to look for them. If you looking for, you know, minor things, less than .001, and you find that basically they're non-genotoxic, you don't -- you leave them alone or you can report them to the agency.

But the purpose of that is USP, you know, sets those limits assuming that anything below it is not genotoxic. You see, there are -- probably 99.9 percent of the impurities are not genotoxic.

Q. But in order to determine whether there are genotoxic impurities, you would need to test

Page 130

every single impurity that appears, even trace impurities below 0.10 percent. Correct?
MR. NIGH: Form objection.
A. Yes, that's correct. You need to test those.
Q. And you're saying that's what pharmaceutical manufacturers were required to do in 2013?
MR. NIGH: Form objection.
A. Absolutely. Let me qualify this. Absolutely. CGMP is really it states to current everything. You know, you have ability to test them, you want -- you need to test them. You know, you have -- GCMS -- I know in 2013 and/or 2014 your client had GCMS at their facility. In fact, they were using it. I know I saw it in some of the documents that I've presented. And why didn't they test it?
Q. Okay. I think we're -- again, we're going a little past -- going a little past the question that we asked, but let me try to focus back in on what we were talking about.
Is it your opinion that every lot of generic valsartan was adulterated even if it did not contain any NDEA or NDMA?

Page 131

MR. NIGH: Form objection.
A. If a valsartan did not contain NDMA or NDEA and met its purity criteria as set by USP, then it's not adulterated.
Q. Okay. So whether generic valsartan was adulterated would depend on whether that specific lot included NDEA or NDMA.
A. Exactly. But I also want to qualify this just as a follow-up to your question. The USP standards that you have in front of you and I've also cited in my report, that USP standard is for Diovan. It's not for ZHP's valsartan. You follow me?
Q. Well, I don't think so.
So your point is the USP valsartan standard doesn't apply to generic valsartan?
A. The USP -- USP valsartan is talking about impurity profile that was present in Diovan, which was using a different, you know, chemistry. It was using tributyltin methodology which was not producing NDMA. But once they changed the process, they should have actually upgraded the USP with their -- essentially, they should have created their own impurity profile.
Q. Okay.

Page 132

A. USP states in one of their general chapters that if you change your synthetic procedure, you need to, you know, essentially have an updated, you know, impurity profile and everything. So what USP doesn't really -- you know, USP is not taking responsibility for anything, and the company cannot rely on that original USP from their brand manufacturer. Not.
Q. All right. We just started talking about the USP general notice. So I want to introduce as Exhibit, I believe, 8, Tab 35.
(Exhibit Najafi-8, USP 35 General Notices and Requirements, No Bates, 13 Pages, was received and marked for identification.)
Q. That's USP 35 General Notice and Requirements.
You were just talking about this. Right?
A. Right. Let me just see.
MS. ROSE: Justin, can we go to Section 5.6.10 on page 4. It's on 4 of the PDF.
A. 5.60.10?
Q. Yeah, 5.60.10. You will see there it says: "The presence of any unlabeled other impurity in an official substance is a variance from the

Page 133

standard if the content is 0.1 percent or greater. The sum of all other impurities combined with the monograph detected impurities may not exceed 2.0."
Do you see that?
A. Yes.
Q. Okay. Do you agree that USP sets the standard that unlabeled impurities in a substance are only a variance from the standard if the content is 0.1 or greater?
A. One second. Let me...
Q. Are you still reading that one sentence, or are you answering my question?
A. I'm actually reading the -- reading the paragraph before it just to get context --
Q. Do you want to go off the record?
A. Oh, no, no, no, no.
Q. It's been about 45 seconds. Just want to -- you told me to tell you when it's 30 seconds.
Are you able to answer my question, Dr. Najafi?
MS. ROSE: I think he's having an audio problem. Can we go off the record. Yeah, he's calling a time-out. He's calling a visual time-out.
THE VIDEOGRAPHER: Let's go off the record, please.

Page 134

(A brief recess takes place.)
(Testimony reread.)
THE VIDEOGRAPHER: The time is 1:18. We're back on the record.
BY MS. ROSE:
Q. Okay. You can answer.
A. I think -- yeah, I think under general chapter, you know, basically same -- same as, you know, 5.60.10. There's -- the answer is there for you.
Q. I'm sorry, you're going to have --
A. Okay?
Q. Can you -- can you clarify that?
A. Any substances known to be toxic, in this case, genotoxic, shall not be listed under "other impurities."
Q. Okay. And where does --
A. This is 5. -- this is 5.60.10. There's other impurities in USP --
(Court Reporter Clarification.)
MS. ROSE: He's reading --
A. To answer your question -- I'm reading. I'm reading from the general chapter. "Any substance known to be toxic shall not be listed under other impurities."

Page 135

Q. Are you saying you're reading that from something?
A. I'm reading it from a general chapter, and basically it's saying toxic impurities do not need to meet the threshold of 0.1 percent, known genotoxic compounds.
Q. Oh, I see. Okay.
A. Do you see that?
Q. I see what you're saying.
MS. ROSE: Can you exit out of -- Justin, exit out of the -- that -- yes. Thank you. I appreciate it.
Q. Okay. Any substance that is known to be toxic, that's what you're reading from. Okay.
A. Right. I'm reading it from the general chapter.
Q. Got it.
It's your opinion that as of 2013, valsartan -- I'm sorry. It was -- your opinion that as of 2013, it was known that there was impurities that were known to be toxic under the 0.1 percent standard in valsartan?
A. No. I mean, we didn't know there was these impurities are out there. I'm saying if they were present, they should have -- they should have

Page 136

looked for it. That's the whole idea. Toxic impurities do not need to meet the threshold, .1 percent threshold.
Q. But you can't know --
A. And are --
Q. I'm sorry.
A drug manufacturer can't know that an impurity is toxic unless it specifically tests for it. Correct?
MR. NIGH: Form objection.
A. Only if -- only if it's an unknown entity. NDMA was not an unknown entity. We've known NDMA for 50 years, at least.
Q. So you're saying that, again, every drug substance manufacturer has to test every single impurity under 0.1 percent to make sure it is not a substance known to be toxic?
A. Yes.
Q. So any drug manufacturer that doesn't test every single impurity, even those under 0.1 percent, is in violation of cGMP?
MR. NIGH: Form objection.
A. That's correct.
MS. ROSE: I just wanted to introduce Tab 51. I think this will be Exhibit 9.

Page 137

THE VIDEOGRAPHER: Right.
(Exhibit Najafi-9, Article entitled: Identification and Control of Impurities For Drug Substance Development using LC/MS and GC/MS, from The Journal of Liquid Chromatography and Related Technologies, was received and marked for identification.)
A. Right.
Q. Have you seen this document before, Dr. Najafi?
A. I believe I have.
Q. Okay. I'll represent to you this was included on a supplemental reliance list that was created by plaintiffs' counsel to defendants on Monday.
A. Right.
Q. And you see this article. It's called "Identification and Control of Impurities For Drug Substance Development using LC/MS and GC/MS." Correct?
A. Yes, that's correct.
Q. And it was published in 2018?
A. Okay.
Q. If you can look at page 3 of the PDF, it has 2236 at the top of the page. At one, two,

Page 138

three -- four lines down at the end of that line, it says that "ICH guideline Q3A(R) requires that organic impurities at or above 0.1 percent or 1.0 milligrams total daily intake, whichever is lower, should be identified for drug substance with maximum daily dose of less than 2 grams daily."

Do you see that?

A. Correct.

Q. Okay. So according to this article, which you cited as something you considered in forming your opinion, it says that under ICH Q3A, organic impurities need to be identified if they are at or above 0.1 percent, or 1.0 milligrams. Correct?

A. That's what the article says, and I believe, you know, any impurities that you can identify on the chromatogram, and it points to even .001 percent impurity and by GCMS, and it shows a genotoxic compound, you have a moral duty to report that and to identify it and to control it.

Q. But according to this, and you cited to Q3 earlier, Q3 only requires the identification of impurities at or above 0.1 percent.

A. I think -- we were talking about organic impurities. We're not talking about

Page 139

genotoxic impurities. I think there's a provision in Q3A -- Q3A and B regarding genotoxic impurities as well, if I'm not mistaken.

Q. So the drug manufacturer would have to know that there is a genotoxic impurity in its drug in order to go and look for it at a level below 0.1 percent?

MR. NIGH: Form objection.

A. So there are two ways that you go about looking for genotoxic impurities. One, we call it targeted. And the second one, we call it untargeted. The way Novartis was looking at their chromatography was untargeted. They were basically looking at every impurity. And they said, We have to identify what these impurities are.

Some of them were less than .1 percent. And that's how they discovered it. A targeted approach is -- it's really done by your organic chemist, by your process chemist. And that typically -- the organic chemist says, hmm, we're using sodium nitrite. We should worry about NDMA and NDEA, period.

Now, let's say nobody can guess that DMF is going to be composed into dimethylamine. Nobody can guess triethylamine is going to convert

Page 140

into NDEA. But because you're using sodium nitrite, you know, all antennas should go up. So that becomes targeted, where now the chemistry team tells the QC team, Could you guys get set up to test for NDMA, NDEA, and also diisopropyl, nitrosol, all kinds of variation, and they do.

This is what Novartis does. This is what, you know, Sanofi-Aventis, my former company, does. You know, we do that. This is routine.

Q. Okay. Again, I think we've gone a different -- I was just asking --

A. I'm just trying to help you understand a little bit.

Q. I understand. I think we're -- you said that anytime a company is using sodium nitrite in its reactions in making a drug substance, that alarm bells should go off and you should test for genotoxic impurities.

Is that your position?

MR. NIGH: Form objection.

A. Exactly.

(Court Reporter Clarification.)

MR. NIGH: Hold on.

Form objection. I'll indicate that he was responsive to the prior question.

Page 141

Q. What FDA regulations or guidance require drug manufacturers to test for genotoxic impurities anytime sodium nitrite is being used?

MR. NIGH: Form objection.

A. FDA is not here to legislate common sense. You know, often FDA tells us, the manufacturer -- or they tell us, tell us how you want to develop the drug. Tell us what your manufacturing is.

They don't tell you -- if FDA were to try to provide guidance for this, for that, we would have so much papers, you know, it's crazy. So this is manufacturer's responsibility.

And I think USP also states in their general chapter -- and I can point it to you -- that once you change the process, it's the manufacturer's responsibility to go above and beyond to make sure, you know, there's proper impurity profile, you know, and there's also proper risk assessment is done.

And risk assessment effectively creates that targeted analysis, where you say, we're using sodium nitrite. We got to use -- we got to check for this, this, this, and that, you know.

Q. Okay. But, again, going back to my question. I think what you just said was the FDA

Page 142

doesn't have any guidance or regulations that say when you're using sodium nitrite, you need to look for genotoxic impurities?
A. No.
MR. NIGH: Form objection.
A. Of course not, yeah.
Q. Okay. All right. I'm going to move back to where we were before, which was: Is it your opinion that the mere presence of NDMA or NDEA in generic valsartan renders it adulterated because the reference listed drugs for valsartan, Diovan, and Exforge do not contain NDMA or NDEA?
A. Because, you know, NDMA and NDEA are genotoxic, their mere presence renders them adulterated.
Q. I think we covered that opinion, and maybe we'll go back to that at some point. But I'm asking about a separate opinion.
You've said that the presence of NDEA or NDMA renders it adulterated because they're genotoxic; that's one. But I'm asking if you have a separate opinion that the presence of NDMA or NDEA in genetic valsartan renders it adulterated because the reference listed drugs do not contain NDMA or NDEA.

Page 143

A. That's correct. Because the reference listed drugs does not contain NDEA and NDMA, then it's -- if it shows up, then it's adulterated.
Q. Okay. So it's your position that Diovan and Exforge have never contained NDMA or NDEA?
MR. NIGH: Form objection.
A. Based on the chemistry of Diovan and because they're not using sodium nitrite, you do not expect to have NDMA or NDEA. And this has been confirmed by Health Canada in their extensive testing of Diovan in Canada, and I think I've cited that in my report as well. So Diovan has shown to be free of any NDMA and NDEA.
Q. And you say in your report that Diovan and Exforge are manufactured by Novartis. Correct?
A. I believe so.
Q. Do you know if Novartis sells any valsartan products other than Diovan and Exforge in the United States?
A. I do not.
Q. You have no reason to believe that they do?
A. I have no reason --
MR. NIGH: Objection to form.

Page 144

A. -- to be, yeah.
Q. I know you've talked at your last deposition about the 2019 citizen petition that was filed by Valisure. Correct?
A. That's correct.
Q. And you're aware that Valisure citizens petition reported that it tested samples of Novartis's valsartan and it contained NDMA. Correct?
A. I'm aware of that.
Q. And you've testified that you were involved in validating some of the testing that Valisure did in connection with the citizens petition. Correct?
A. That's correct.
Q. And you submitted a declaration in this litigation in 2022 stating that you were sent some of the samples that Valisure tested and you validated their results. Right?
A. We were blinded to Valisure's testing, so we have no idea what we tested. Basically they sent us pills. They said, please test these for NDMA. We gave them results. So what they gave to us were codes, effectively.
And then later, they said these were

Page 145

this, that, and so forth. And we don't know whether they reported our results at all, you know, but they -- they had -- we had worked with them.
Q. How many samples from Valisure did you test?
A. I cannot tell you right now. It was -- we can look that up. I don't know. I don't think it's more than maybe somewhere between ten to hundred, maybe.
Q. Okay. Did you make any effort to investigate that when you were writing your declaration?
A. No.
Q. Did you validate Valisure's results for all of the samples that you did test?
MR. NIGH: Form objection.
A. As I mentioned to you, we simply tested for NDMA using GCMS not knowing what we're testing. So, you know, we knew, according to Valisure -- or Valisure that they were -- it was valsartan. But we really couldn't tell what -- valsartan from who, who was the manufacturer.
Q. Okay. That -- again, not what I was asking. I was just asking when you -- whatever, whichever results you got, that ten to a hundred

Page 146

samples and you retested, did you get the same results as Valisure?
MR. NIGH: Form objection.
A. If I'm blinded to what the data -- you know, what they're sending to me, how would I be able to know --
Q. So you had no --
A. -- if it's validated?
Q. You just gave them your samples?
A. We just gave them the results.
Q. And if your results differed from their results, would they have contacted you?
A. They basically told us that we're in the ballpark; that's the terminology they used.
Q. Was this in a written communication?
A. In other words, you know, I think, you know, it could have been telephone, telephonic communication. I can't recall.
Q. Okay. But they -- they communicated to you that the results that you reached on the ten to a hundred samples you tested were in the same ballpark as the results they reached in their citizens petition. Correct?
A. That's correct.
Q. Okay. Had you or Emery Pharma worked

Page 147

with Valisure prior to validating their valsartan testing in 2019?
MR. NIGH: Form objection.
A. No.
Q. They approached you out of the blue?
A. No, we had met actually a couple of years before that, actually at the J.P. Morgan healthcare conference, at a conference.
Q. When you says "you had met," was it someone in particular at Valisure?
A. With the CEO of Valisure.
Q. Is that David Light?
A. David Light, yeah.
Q. You were friendly with David Light?
MR. NIGH: Form objection.
Q. I'm sorry, I didn't hear your answer.
A. Yes.
Q. Have you or Emery Pharma worked with Valisure since you validated their testing for the 2019 citizen petition?
A. Since our work with valsartan, we also supported a little bit of their work with Zantac as well, and --
Q. What do you mean by "support"?
A. And I believe --

Page 148

Q. I apologize if I cut you off. I didn't mean to. I thought you were done.
A. Yeah, so, no, so we did the valsartan project, I think, in early 2019, or maybe 2018, I don't remember. And then, then we actually looked at their testing for Zantac which they wanted us to run GC, GCMS for Zantac, which we did. And we did not agree with the way Zantac should be tested by GCMS, and then -- they went on and filed the petition, but we were not involved with their petition for Zantac at all.
Then we also did some benzene testing for them or maybe -- maybe we got an inquiry from them for benzene and in sunscreen.
Q. Got it.
And have you ever asked Valisure to validate any findings from your lab?
MR. NIGH: Form objection.
A. No.
Q. Do you respect Valisure as a laboratory?
MR. NIGH: Form objection.
A. What do you mean by "respect Valisure as a laboratory"?
Q. Do you think -- would you say it's a

Page 149

respected laboratory?
MR. NIGH: Form objection.
A. Valisure is a pharmacy. I respect them as a pharmacy.
Q. Okay. So you don't -- does Valisure do testing?
A. No.
Q. So is it your understanding that the testing that was done to support the 2019 citizens petition was not done by Valisure?
A. Valisure has some analytical equipment. I believe they did the testing themselves, but they're not -- I would not consider them as a, you know, a contract research testing lab. And they are a pharmacy that tests their -- sort of their goal is to test every drug they sell for their customers.
Q. Okay. Would you say that you respect the scientists who work at Valisure as scientists?
MR. NIGH: Form objection.
A. Yeah, I respect the scientific team at Valisure.
Q. I want to introduce -- I'm going to say Exhibit 9. I could be wrong. It's Tab 17.
(Exhibit Najafi-10, PowerPoint Presentation entitled, "Where is NDMA Coming From?

Page 150

Root Cause Analysis" No Bates, 25 Slides, was received and marked for identification.)

(Exhibit Najafi-11, LibreTexts Document on Sodium Azide, No Bates, One Page, was received and marked for identification.)

(Exhibit Najafi-12, Book entitled, Purification of Laboratory Chemicals by W.L.F. Amarego and D.D. Perrin, 544 Pages, was received and marked for identification.)

THE VIDEOGRAPHER: This should be Exhibit 10.

MS. ROSE: Oh, Exhibit 10, thank you very much.

Q. Dr. Najafi, these are slides for a presentation about NDMA in ranitidine that you presented at an industry conference in 2020. Correct?

A. This does look like it is my presentation.

Q. And this is listed on your CV. Correct?

A. I don't know.

Q. You presented at that conference about the mechanism by which you think NDMA can form in connection with ranitidine. Is that correct?

Page 151

A. Yes, I believe so.

Q. And as we have discussed, you were a paid expert in the ranitidine litigation?

A. Yes, I was.

Q. But your expert -- your opinions were excluded there. Correct?

A. All experts' opinions on ranitidine case were excluded through a Daubert hearing which essentially shows that it's -- by and large, it's about, you know, connection within, you know, NDMA and cancer. But that's not my area of expertise, and that's how -- that's how the exclusion occurred, but the data that we generated and presented is absolutely valid and reliable and will be published.

Q. Okay. I just want to be clear, are you aware that the Court in ranitidine specifically looked at your opinions and the testing that you conducted and excluded it?

A. I was one of the experts that they excluded.

Q. Yes. I'm aware, but I just wanted -- it sounded like you were saying all experts were generally excluded based on something that had nothing to do with your opinions, but I just wanted to make sure, have you read the opinion that

Page 152

excluded your -- the testing you performed in connection with ranitidine?

MR. NIGH: Form objection.

A. I haven't read it in hundred percent detail, but I scanned through it.

Q. You're aware the Court there found in the testing that you conducted was unreliable. Correct?

MR. NIGH: Form objection.

A. I disagree with the Court's conclusion and -- but, you know, basically all experts were excluded. Again, I'll repeat that.

Q. I appreciate you repeating it, but I -- I don't think you answered me.

Are you aware that the Court looked at your testing and excluded your opinions based on your testing on the grounds that it was unreliable?

MR. NIGH: Form objection.

A. I disagree with their conclusion.

Q. Okay. All right. I -- were you paid to make this presentation at the industry conference in 2022?

A. No.

Q. If you turn to the last slide in the presentation. It is their acknowledgments. The

Page 153

Emery Pharma team is mentioned, including Dr. Bose, who you said has helped you in forming your opinions in this case.

Did any of the other Emery Pharma team members listed here, who we have not previously discussed, helped you in any way with forming your opinions in writing your report for this case?

A. No.

Q. In your acknowledgments for this preparation, you also mention the Valisure team. Correct?

A. That's correct.

Q. And you specifically mentioned David Light and Dr. Kaury Kucera. Correct?

A. Correct.

Q. Are you aware that David Light and Kaury Kucera were the two individuals who signed the Valisure 2019 citizens petition about valsartan?

A. Correct.

Q. Was it one of these two people who asked you to validate the citizens petition testing?

MR. NIGH: Form objection.

A. David Light is our primary contact.

Q. And then you, a year later, asked them to help you prepare an industry presentation on

Page 154

ranitidine. Correct?
MR. NIGH: Form objection.
A. Would you repeat your question?
Q. Sure.
After David Light asked you to validate the testing underlying the citizens petition in 2019, you asked David Light and members of his team to help you prepare an industry presentation on ranitidine?
A. No, that's not correct.
Q. Does this presentation rely on any testing performed by Valisure?
A. Would you show me the presentation?
Q. Sure. You have access to it.
MS. ROSE: But, Justin, could you also click through it.
THE WITNESS: Could you just flip through it, and slide number 1, slide number 2. Okay. That's my background, keep going. NDMA, keep going. Keep going. NDMA, okay, okay.
A. So this presentation is entirely about NDMA and ranitidine. It has nothing to do with valsartan. And the industry people that I've known for many years, they contacted me and they said, Would you like to present at this event? And when I

Page 155

mentioned to them that this is what's going on with ranitidine and valsartan, they also went and sought David Light, and, you know, various other individuals. I believe there was a USP person also on a panel. So there was a -- multiple people, you know, on the presentation thing, and I presented this, yes.
Q. Okay. Appreciate that, not my question.
My question was: Does your presentation rely in any way on testing performed by Valisure on ranitidine?
A. Zero.
Q. So they didn't help you prepare your preparation. You didn't rely on their testing.
Why did you acknowledge them at the end of your presentation?
MR. NIGH: Form objection.
A. It's a good question. Because they sort of introduced us to the problem of ranitidine potentially generating NDMA.
Q. And when was that?
A. When was that? I think it was back in maybe August of 20 -- 2019.
Q. All right. So you kind of formed a

Page 156

trust with Valisure because they alerted you to a problem. Then you researched and became an expert in litigation with respect to it.
MR. NIGH: Form objection.
A. We --
(Court Reporter Clarification.)
A. That's correct.
Q. Have you ever asked Valisure whether the Novartis samples that they tested and in which they found NDMA were Diovan and/or Exforge?
MR. NIGH: Form objection.
A. Frankly, I did not really care too much to know about it. As I mentioned to you before, this is not anything -- you know, we're not -- this is not the only thing we're doing at Emery Pharma. So at any one time I have probably two dozen other projects at Emery Pharma, biologic project, drug development project.
So basically, when he came to, he called me and said, Hey, can you test these things? And we did it probably, you know, just as a favor to him and send him the data. And I didn't really dug into what is what and all that.
And at the time, it was really beginning of valsartan situation, and I wasn't too

Page 157

aware of all the various controversies and various things.
Q. Okay. So you said earlier that you are offering the opinion now in 20 -- we'll say now it was in your 2022 report, but you're offering your opinion at this deposition that generic valsartan was adulterated because it contained NDEA or NDMA and the reference listed drugs, Diovan and Exforge, did not.
And you were aware that the 2019 citizens petition by Valisure found NDMA in a Novartis product. Is that all correct?
MR. NIGH: Form objection.
A. I wasn't aware of valsartan results, and when they put it in their -- their citizen petition, I might have even not read their citizen petition.
Q. When did you read the 2019 citizens petition?
A. Probably sometime in 2020.
Q. Okay. So but you're offering the opinion now -- or you offered the opinion in an October 2022 report that Exforge and Diovan do not contain NDMA. And you offer that opinion --
A. That's correct.

Page 158

Q. -- knowing that in 2019, Valisure found NDMA in a Novartis product?
MR. NIGH: Form objection.
A. Very good question again, Nina. It's a puzzle for us -- for me, because I do not expect Diovan and Exforge -- if they're using that synthetic methodology, I do not expect NDMA in their process.
But having said that, you know, I don't know, I wasn't -- I don't know what Novartis -- whether Novartis bought API from somebody, put it together under this. A lot could happen.
But original valsartan process, which is the tributyltin azide, does not lend itself to produce NDMA because no sodium nitrite issues. So I'm puzzled. I think there might have been some mistake made perhaps by Valisure in their testing.
There could have been a cross-contamination during that testing. It could have been a labeling error. It could have been, you know, Novartis effectively buying some contaminated API and putting it into their finished product. It's all speculation.
Q. That was the exact word I was about to use. So this is all speculation. You don't know if

Page 159

any of that happened, but that's just your speculation of what might occur?
MR. NIGH: Form objection.
(Court Reporter Clarification.)
Q. Sorry, I thought you said yes. Right?
A. It is all speculation on my part because the Exforge and Diovan process, which utilizes tributyltin azide and doesn't utilize sodium nitrite, should not produce NDMA and --
Q. Sorry.
A. -- and Health Canada in their many testing -- and I have a little bit more -- how I should say? I don't want to say respect. I have a lot more trust in Health Canada's testing, which they showed that Diovan is free of any NDMA.
Q. Have you ever --
A. Now --
Q. -- done any -- sorry.
Have you ever done any testing to validate results obtained by Health Canada?
A. We have -- I think as part of our disclosure, we have -- been retained by a Canadian lawyer. We actually ran some testing of their pills. They sent us pills from their patients. We ran them, and we don't know what those pills -- who

Page 160

are the manufacturers of the pills. But many, many of them contained large amounts of NDMA.
Q. Sorry, I want to clarify what we were just talking about.
So you're saying a Canadian lawyer contacted you to test valsartan pills?
A. Right.
Q. When was that?
A. I think it was before Valisure contacted us. 2018, sometime in 2018, late 2018.
Q. And you don't know what medications you were testing. It could have been Exforge or Diovan?
MR. NIGH: Form objection.
A. Could have been Exforge, Diovan. It could have been anything.
Q. So you can't say what type of valsartan you found NDMA in?
A. I cannot.
Q. Have you ever -- has your lab made any attempt to test Exforge or Diovan to determine if it includes any NDMA or NDEA?
A. We were not asked by the current plaintiffs to do any testing for them. So we have not, and we have not taken it upon ourselves to do any testing either.

Page 161

Q. Wouldn't that testing resolve this dispute and solve the puzzle?
MR. NIGH: Form objection.
A. Testing Diovan?
Q. Yes. You said there was a puzzle as to why Valisure found Diovan.
A. Yes.
Q. Wouldn't it solve the puzzle if you yourself tested Exforge or Diovan to see if there was any NDMA --
MR. NIGH: Form objection.
(Court Reporter Clarification.)
MS. ROSE: Sorry. I said -- I can't remember the beginning of the question.
(Question read back.)
Q. Sorry.
You said that there's a puzzle as to why Valisure found NDMA in Diovan or Exforge. Wouldn't it solve the puzzle if you yourself tested Diovan and Exforge to see if it contains NDMA?
MR. NIGH: Form objection, mischaracterizes his testimony.
A. I think it's already done by an authority, which is namely Health Canada, already has shown that Diovan doesn't contain NDMA.

Page 162

Q. Has anyone ever instructed you not to conduct testing on Exforge or Diovan?
A. No.
Q. So you're relying entirely on Health Canada's results on opining that Diovan and Exforge do not contain NDMA or NDEA?
MR. NIGH: Form objection, mischaracterizes testimony, asked and answered.
A. I am relying a hundred percent on Health Canada, and I trust -- I trust as much as I trust FDA.
Q. And do you know if -- did Health Canada test both Canadian and U.S. supply of valsartan?
A. I don't recall right now, but I've cited them. I think it's Diovan -- Canada Diovan, I believe. I don't know. We have to check.
Q. But it wouldn't surprise you if Health Canada tested Diovan that was sold exclusively in Canada?
A. It doesn't matter. Diovan, I mean, there is no -- you know, it's the same pill. They ship it across the border.
MS. ROSE: All right. I'm about to go into a new section. I know that -- for me it's late, but for you, it's past lunchtime. Do you want

Page 163

to take a break for some lunch?
THE WITNESS: I already have. I'm good. I'm just worried about Ellen, if she wants to take maybe a quick bio break.
COURT REPORTER: Thank you, Doctor.
THE WITNESS: I'm good. We can continue.
(Court Reporter Clarification.)
MR. NIGH: Let's take a 15-minute break.
MS. ROSE: Okay.
THE VIDEOGRAPHER: The time is 2:02. This ends Media Unit Number 3. We are off the record.
(A brief recess takes place.)
THE VIDEOGRAPHER: The time is 2:25. This begins Media Unit Number 4. We're back on the record.
BY MS. ROSE:
Q. Dr. Najafi, did you talk to anyone while we were on a break?
A. I talked with Rosemarie and Daniel.
Q. Okay. And did you look at any documents while we were on the break?
A. No.

Page 164

Q. I may have asked this earlier, but I think I may have skipped it.
Do you know who Kali Panagos?
A. Who.
Q. Panagos, P-A-N-A-G-O-S, does that name mean anything to you?
A. Never heard of it.
Q. Okay. Thanks.
I want to talk briefly about the valsartan synthesis process, generally. You've said this earlier, but ZHP used different processes to manufacture its valsartan API over time. Correct?
A. That's correct.
Q. And you -- I'm so sorry. I'm watching your nods and not waiting for you to answer.
You said the first process was the TIN process. Correct?
A. The TIN process was the process that valsartan was approved on. So the approved drug was valsartan TIN process.
Q. All right. And it's your opinion that the tin manufacturing process could not result in the production of NDMA or NDEA.
A. Based on my 40 years of experience as a synthesis organic chemist, I do not expect the TIN

Page 165

process to generate NDMA, because sodium nitrite is absent. And the product was approved by the FDA, God knows when, 20 years ago, and the USP is by and large based on that process.
Q. And the next process that ZHP used is the TEA process. Correct?
A. That's correct.
Q. And that process used triethylamine hydrochloride in Step 4 of the valsartan manufacturing process. Right?
A. That's correct.
Q. And that process was documented with the FDA in Drug Master File 23491?
A. That's correct.
Q. Is it your opinion that the TEA manufacturing process documented in the original Drug Master File 23491 could result in the formation of NDMA or NDEA?
A. If the process and -- if the process involves sodium nitrite, absolutely.
Q. All right. Is it your understanding that the TEA manufacturing process documented in the original Drug Master File 23491 involved sodium nitrite?
MR. NIGH: Form objection.

Page 166

A. Yes, it does.
Q. Okay.
A. Sorry, I spoke too soon.
Q. Oh, it's all right.
Is it your understanding that ZHP made an amendment to the drug master file for the TEA process that added a quenching procedure after the tetrasol reaction with sodium nitrite solution/hydrochloric acid?
A. My understanding.
Q. Okay. Before that amendment was made to add the quenching procedure after the tetrasol reaction, did the TEA manufacturing process involve sodium nitrate?
A. I have to look at my report. I believe it did.
Q. Okay. Well, look at your report. It's Tab 7.
MS. ROSE: And Justin is going to have to remind me of the exhibit number. You can go back.
THE VIDEOGRAPHER: 7.
MS. ROSE: Sorry. If you want to put up Exhibit 7, page 19. That's 19 of the actual result, actual report, not 19 of the PDF, if you

Page 167

look at the page numbers on the bottom.
Q. All right. You see there that it says the ZHP moved away from the TIN process and submitted a DMF 23491 for the TEA process of January 2010, and then that process changed Step 4 by using triethylamine.
A. Right.
Q. Correct?
A. Right.
Q. But it's your opinion that that process changed, adding triethylamine, used sodium nitrite?
MR. NIGH: Form objection.
A. They used -- if you continue reading after triethylamine, it says: "... by using triethylamine hydrochloride, sodium azide," instead of tributyltin fluoride and sodium azide.
Q. So are you saying the sodium azide is the same thing as sodium nitrite?
A. No.
MR. NIGH: Form objection.
A. Sorry. So when you use sodium azide, you have to neutralize it with a neutralizing agent, and the neutralizing agent is often sodium nitrite.
Q. Okay. But do you have any evidence that in the original TEA process under the original

Page 168

DMF 23491, that ZHP was using sodium nitrite as a neutralizing agent?
A. Based on what documents I've reviewed, it shows that they're using sodium nitrite to neutralize sodium azide.
Q. Okay. Let's look a few lines down. You say: "ZHP filed another amendment to DMF 23491 adding a quenching procedure after tetrasol reaction with sodium nitrite solution/hydrochloric acid to guarantee azide is destroyed thoroughly and to minimize the risk of residual azide carryover into the final drug substance on April 16, 2012."
Correct?
A. Right.
Q. So prior to April 16, 2012, sodium nitrite was not being used in the manufacture of ZHP's valsartan?
A. I'm -- you know, I have to look at it carefully. Basically, ZHP decided to move away from using the TIN process and submitted a DMF for the TEA process in January 2010, and then TEA process changed Step 4, crude step, by using triethylamine hydrochloride sodium azide instead of tributyltin chloride sodium azide.
So essentially they got rid of the

Page 169

tributyltin azide process. But to get rid of the sodium azide, sodium azide is an explosive agent, and also not only that, sodium azide on its own is very toxic, so they have to get rid of it. And to get rid of it -- I don't think they clearly indicate what they're doing in that process. But they must be using sodium nitrite.
And then basically we're saying in response to the DMF deficiency from --
(Court Reporter Clarification.)
MS. ROSE: Yeah, I think he's -- you're just reading from the document.
A. Sorry.
Q. It's okay. I see what you're saying. I'm just trying to make a point of it's very simple.
MR. NIGH: Can you let him finish his answer?
MS. ROSE: Sure. He's just reading from the document at this point.
A. I think the bottom line is -- this is what's going on. If you use tributyltin azide and you don't use sodium nitrite, you're safe. The moment you use sodium nitrite, then you're going to get NDMA.
And in this case, they used large

Page 170

excess of sodium azide in one of their subsequent filings and processes. They filed with the FDA that we need to -- they're improving the yield. They're trying to increase the yield, and so they're just generating lots and lots of sodium -- lots of sodium azide they're using, and they have to neutralize it.

Sodium azide is an explosive and it's also toxic, so they have to neutralize it; otherwise, we'll have other problem in the final product. We're going to end up with some sodium azide in the valsartan product.

Q. All right. I just want to be clear as we're talking about the manufacturing processes. How about this? If I refer to the TEA process that -- I was going to refer to it as the TEA with quenching process because that's how you refer to it in your report.

Is it fair if I call it the TEA quenching process that refers to TEA using sodium nitrite to quench the azide solution?

A. They use azide. They have to quench it with sodium nitrite.

Q. I'm just trying to get a definition. If I say "TEA with quenching," I'm referring to the TEA process using sodium nitrate. Is that fair?

Page 171

A. Okay.

Q. Okay. Great.

A. Yes.

Q. Is it your opinion that TEA with sodium nitrate -- or I'll say TEA with quenching process can result in the formation of NDMA?

A. Yes.

Q. Okay. Where is that opinion stated in your report?

A. It's in there somewhere.

Q. And to be clear, I'm talking about the TEA with quenching process causing NDMA.

A. Let me look through my report and I can tell you.

Q. Okay. We can go off the record and -- do you want to go off the record and you can look through your report to see if you have that opinion?

A. No, I don't want to go off the record. I should be able to find it quickly.

Q. Before you look at your report, I just want to know, you can't say right now, without an in-depth review of your report, whether it's your opinion that the TEA with quenching process causes the formation of NDMA?

MR. NIGH: Form objection, it's been answered.

Page 172

MS. ROSE: It has not.

MR. NIGH: It has been.

A. TEA with quenching process generates NDMA.

Q. Yes. Is that your opinion? Without looking at your report --

A. That's my opinion.

Q. -- that's your opinion. Okay.

Let's go off the record. You can look at your report and you can show me where it says that in the report.

MR. NIGH: I don't agree to those terms. If you want him to look at his report to point something out to you, that's on the record.

Q. Okay. How about -- let me do it this way: Can you explain to me the process by which the TEA with quenching process results in the formation of NDMA?

A. And I -- repeat your question.

Q. Sure. I'm just looking for an explanation of the process by which TEA can react with sodium nitrate to perform NDMA.

A. So this is laid out in my report. I think I have even a chemical reaction, you know,

Page 173

associated with it.

Q. Okay.

A. So let me -- so this is what happens. When you treat the triethylamine hydrochloride, and you have sodium nitrite and hydrochloric acid, sodium nitrite converts to nitrous acid, HNO2. HNO2 gets degraded into NO+, nitrosonium compound.

Nitrosonium molecule gets reacted with triethylamine and forms triethylamine and nitrosonium, or nitrosated triethylamine. It's in my report. And then you lose a -- you lose a basically HNO, and then it forms a double-bonded moiety with an N+.

And then it reacts with water, and forms a -- sort of a ketal moiety with nitrogen. So there's -- every time you have two hetero atoms on a carbon, it's a very unstable molecule. So you lose an acid aldehyde, which by the way, is also a carcinogen. And then now you form diethylamine. Now it's the beginning of diethylamine reacting with another nitrosonium ion, and now it forms NDEA.

Q. Okay. I appreciate that understanding, but at the end of that you ended with "NDEA."

A. It's on my -- it's on page 24 of my report.

Page 174

(Court Stenographer clarification.)
MS. ROSE: I'm sorry, Ellen. Did you need something?
COURT REPORTER: No. I'm fine.
MS. ROSE: Okay.
Q. I appreciate that. But page 24 of your report shows the process by which the triethylamine hydrochloride process can result in NDEA.
My question was: Can it result in NDMA, that I asked several times?
A. No, it cannot.
Q. Okay. I asked that question several times, and I said "NDMA." So I'm just confused.
A. Oh, I'm sorry. I think either I misunderstood or you misspoke.
Q. Okay.
A. But if you have triethylamine, you're going to end up with NDEA.
Q. Okay.
A. If you have a dimethylamine, you're going to end up with NDMA.
Q. Now we're on the same page. So my follow-up question is -- I don't know if it's a follow-up question, but -- or maybe it's the same question.

Page 175

Can the TEA with quenching process result in the production of NDMA? Not NDEA. Sorry to talk over you.
A. No.
Q. No is the answer?
A. No.
Q. Okay. Great. And I'm --
A. However, however, I want -- I need to qualify it. Okay? Because if you're using -- basically, if anywhere there is a diethylamine present, you know, you're also going to end up with -- if DMF is part of the process, you're going -- DMF is your contributor to NDMA, and triethylamine is your contributor to NDEA.
Now, there's also one caveat, please. You know, we've got to put that in the record.
The caveat is that if you used contaminated solvents -- now, because I read, you know, somewhere in various documents that I reviewed that a lot of -- there are a lot of toluene was redistilled and used, and so if you use contaminated solvents, you're going to end up contaminating your process. Now you're going to end up NDEA, NDMA and not know where they came from.
Q. Is it your opinion that the NDEA and

Page 176

NDMA that have been found in ZHP are the result of contamination of the solvents used in the manufacturing process rather than a product of the manufacturing process itself?
A. By and large, the process is generating NDMA and NDEA because of the introduction of DMF, which leads to trimethylamine and triethylamine, which leads to NDEA.
But having solvents that are interacting with all this moieties, the solvents -- because the amounts, the levels are so low, solvents will pick them up and then introduce them into other -- you know, if they're using it even for -- if they go back and use a TIN process with a contaminated solvent, the TIN process is going to get contam- -- you're going to get NDMA and NDEA.
Q. Have you done any investigation as to whether the solvents used by ZHP in the TIN process, the TEA process, or the zinc chloride process were contaminated?
A. I was not asked to give -- to do any investigation in that regard.
MR. NIGH: Form objection.
A. Not, you know, in my lab. But I investigated it, you know, by looking at documents,

Page 177

and it's clear that solvents got contaminated with NDMA and NDEA.
Q. Is it your opinion that ZHP knew that its solvents were contaminated with NDMA and NDEA?
A. Not -- I'm not certain if they knew or they didn't -- they didn't know, but, you know, one thing that I considered was the fact that they weren't qualifying. They're recycled solvents in the proper way. They didn't have proper specifications.
Back in the day when I worked in the lab, in fact in Philadelphia, Rhône-Poulenc Rorer, which became Sanofi-Aventis, we were acutely aware of potential of recycling solvents, and we -- and recycling solvents is absolutely a good thing.
But you got to make sure you're not carrying contamination from one drug to another drug.
Q. Is your -- is an opinion you're offering in this case that ZHP violated cGMP by recycling solvents?
MR. NIGH: Form objection.
A. My opinion is that ZHP did not follow good, you know, cGMP processes as it relates to qualifying their solvents, and I believe there were

Page 178

some -- you know, basically citations as it relates to their procedures, their equipment. Their equipment was not qualified, which is, you know, a big sin.

You know, so here's a manufacturing company to have an equipment that's not qualified; you know, they have to undergo IQ or QPQ. And so I read some of the comments from the FDA inspectors, and, you know, it was -- I wasn't surprised that they -- they were -- they had contamination in their solvents.

Q. Okay. But I don't think that answered my question, which is whether it's your opinion that ZHP violated cGMP by failing to detect contamination in their solvents?

MR. NIGH: Form objection.

A. I believe they did.

Q. And is that your opinion set forth in your report?

MR. NIGH: Form objection.

A. I believe so. You just -- you will search for solvents contamination, contamination of solvents. I can do that too.

Q. Well, we'll move for a second. I want to go back to TEA. You provided a really -- an

Page 179

explanation of all of the different steps that are required to get from the TEA with quenching process to NDEA, which we finally -- which we finally got to. So I want to talk a little bit about that.

Okay. Let's see, on page 27 of your report, where you're talking about -- okay. So one thing we've talked about is that -- you've talked a lot, is that the use of sodium nitrate should have triggered a knowledge that there was a potential for a nitrosamine formation.

I want to draw your attention to the last paragraph of 27, where it says: "There's a substantial" -- oh, I'm sorry. Before I get into the -- before I get into the quote.

And so you talked about, when you were reviewing all the steps that it takes to get from triethylamine to NDEA, that one of the steps is that you're going to eventually have -- the sodium nitrite is going to turn into nitrous acid, and then the nitrous acid is going to turn into a positively charged nitrosonium ion. And then at that point, it's going to react with the triethylamine. And then --

A. Right.

Q. -- it's going to change the

Page 180

triethylamine into another compound. Is that correct?

A. It transforms triethylamine into diethylamine.

Q. Then the diethylamine reacts again with the positive nitrosonium ion to get you NDEA. Correct?

A. Correct.

Q. I'm not a chemist, so you got to give me credit for following.

MR. NIGH: Form objection.

A. But you're doing a good job.

Q. Okay. So I want to go back to -- there is -- okay. So we're talking about the quenching. There's a substantial risk during the step that nitrous acid is formed, which can nitrosate triethylamine, diethylamine and form NDMA as well as nitrosate triethylamine or diethylamine to form NDEA. This a well-established textbook reaction that should be recognized by process chemists working in the pharmaceutical industry for companies like ZHP.

Then there's a cite there. And I wanted to go to that cite, which is -- let's see, Tab -- let me find my tab, 22.

Page 181

I'll represent that this document was produced to us by plaintiffs' counsel on Monday. This is a one-page document. It's titled "Sodium Azide." Correct?

A. Okay.

Q. Do you see the document?

A. Right.

Q. Do you see anywhere in the document where it discusses nitrosation or the formation of nitrosamines?

A. No.

Q. So the only relevance to the paragraph that I just read from your report is that this document says that sodium azide can be quenched with nitrous acid. Correct?

A. That's correct.

Q. And as we've discussed, nitrous acid itself cannot nitrosate triethylamine or diethylamine. It has to give off a positive nitrosonium ion, and that's the actual nitrosating agent for NDEA. Right?

A. Right.

Q. This website doesn't say that the formation of NDEA from triethylamine or diethylamine is a well-established textbook reaction. Right?

Page 182

A. Right.
Q. Is it your opinion that it's a well-known textbook reaction that nitrous acid can nitrosate --
(Court Reporter Clarification.)
Q. Sure. Is it your opinion that it's a well-known textbook reaction that nitrous acid can nitrosate triethylamine and then form diethylamine and then react with a positive nitrosonium ion to form NDEA based on anything other than this web page about sodium azide that you cited in your report?
MR. NIGH: Form objection.
A. I think that might not be the right citation, and if you don't mind, I'll provide you with the right citation during the break.
Q. Okay. We can discuss that when you provide the citation. We can look at it.
But you're saying this doesn't support your opinion; this was incorrectly cited?
A. No, that is an incorrect citation.
Q. Okay.
A. I have the proper citation.
Q. Okay. Great. We have not -- I want to say it on the record. We have not seen that. That was not submitted with your report or in the

Page 183

materials that were provided to us on Monday. So we might need some time to look at that to question you about it.
A. Right.
MR. NIGH: Form objection.
Q. Is it your opinion that as of 2012, when the TEA with quenching process was submitted to the FDA, that every process chemist at ZHP who looked at that process should have raised concerns that TEA would react with sodium nitrate to form NDEA?
A. Triethylamine and -- you know, I think -- I think sodium nitrite, just searching sodium nitrite and the neutralization of sodium azide with sodium nitrite should have raised a lot of antennas within the chemistry, within their medicine or chemistry department, within their process chemistry department, yes.
Q. Okay. And but I have -- you're going to supply us with the cite for that, but I'm just wondering how would process chemists have known that? What -- what source would they have known that triethylamine?
MR. NIGH: Objection.
A. Triethylamine is a cited literature

Page 184

reaction.
Q. It's a cited literature reaction that TEA can react with sodium nitrate to form NDEA.
A. That is correct.
Q. And did you cite that literature in your report?
A. As I mentioned to you, I'll get that citation to you during the break.
Q. Okay. I'm not sure if you answered my question.
Is it your opinion that as of 2013, ZHP should have known that TEA with quenching could lead to the formation of NDEA just from seeing the sodium nitrate and the TEA in the process?
A. I think you asked that question and I answered it, and I'll answer it again.
By virtue of the fact that the team at ZHP is using sodium nitrite, by itself, that should have raised a lot of antennas, and they should have worried about sodium, they should have worried about NDMA, they should have worried about the NDEA, they should have worried about, you know, probably isopropyl alcohol nitrosated amine. They should have worried about hosts of different nitrosamines, and I don't think they did.

Page 185

Q. Is that true of every chemist who at the finish dose manufacturers who looked at the TEA with quenching process?
MR. NIGH: Form objection.
A. Every chemist that uses sodium nitrite -- in fact, Dr. Min Li in his deposition, he brings this up. This is in my report; you know, I think it's on page 29. I discussed that.
Q. I just want to interrupt --
A. Min Li --
Q. I'm so sorry. I'm just trying not to interrupt you. You're now talking about Min Li who's at ZHP, and we were just talking about ZHP. But I asked a very specific question about finish dose manufacturers.
So I'm just asking: Is it your opinion that as of 2013, finish dose manufacturers who looked at the TEA with quenching process should have known that it was going to result in the production of NDEA?
A. Finish dose manufacturers, if they had access to the DMF, they should have -- you know, they should have been aware of the chemical process. Sometimes chemical process is maintained confidential, but the finish dose process typically

Page 186

do untargeted analysis, and -- which is what Novartis did. Very simple.

And then once they qualify the material, then they go and do -- then they -- you know, they essentially come up with a quality agreement between the finish dose manufacturer and the API manufacturer. And furthermore, then they send the QA team to China to do an inspection. If they failed to do any one of those things, they're at fault.

Q. Okay. Again, my question wasn't about what they investigated. I was just saying if they were to look at the manufacturing process and saw sodium nitrite and triethylamine, should they have known that NDEA was a likely result of that process, the finish dose manufacturers? That's all I'm asking, if that's your opinion.

A. You have to ask your question in a different way.

Q. Maybe I'll just ask it from the perspective, is it your opinion that any reasonable chemist who looked at --

A. Right.

Q. -- the TEA with quenching manufacturing process saw that it involved triethylamine and that

Page 187

it involved sodium nitrate should have expected that NDEA would result from the process?

I'm asking if that's your opinion.

A. If they did their due diligence, yes.

Q. Okay. And would the same apply to the chemists at the FDA who reviewed the TEA with quenching process as part of its review of the ZHP drug master file and the ANDAs that relied on that drug master file?

MR. NIGH: Form objection, misrepresents facts in evidence.

A. Could you repeat the question again?

Are you talking about the FDA?

Q. Yeah, you just said that chemists who did their due diligence would have seen the TEA with -- TEA with quenching manufacturing process, seen that it included triethylamine and sodium nitrate and should have known that it would result in the production of NDEA.

I assume you believe that there are reasonable chemists at the FDA. So if a chemist at the FDA who was reviewing the manufacturing process for TEA with quenching, should they have known --

A. Right.

Q. -- that it would result in the

Page 188

production of NDEA?

MR. NIGH: Form objection.

A. The chemists at the FDA are not responsible for the manufacturing because they're not there on a day-to-day basis. They approve a process, okay. And in this case, they approved a process -- the CMC chemist at FDA approved and -- reviewed and approved the process that, you know, effectively approved Exforge and Diovan. That process was tributyltin. There was no sodium azide -- there was no sodium nitrite.

And, you know, fast-forward to going off patent and going generic and your client now changing the process. You know, it's very possible that the same thoroughness of review is not done at the FDA. And FDA always tells you they're not responsible for your screw-up. It's your -- it's the manufacturer's responsibility. So perhaps they missed it.

Q. Okay.

A. And I'm -- yeah.

Q. I understand your response, but if -- I understand that you are a -- you, again, did not work at the FDA in 2013 through 2018. Correct?

A. Right.

Page 189

Q. You were not involved in the review of the ANDAs for valsartan generic products using -- that were manufactured using the TEA with quenching products. Correct?

A. Correct.

Q. And you were not involved in the review of the DMF submitted by ZHP that set forth the TEA with quenching process. Correct?

MR. NIGH: Form objection.

A. I was not at FDA.

Q. So you can only speculate that the FDA missed it when reviewing those documents, that they missed the entire manufacturing process for the TEA with quenching manufacturing process system.

MR. NIGH: Form objection, argumentative.

(Court Reporter Clarification.)

A. I am saying FDA -- it's not really FDA's job to do a thorough analysis of everything. They do somewhat of a, you know, cursory look at the chemistry, the reaction, and they ask a lot of questions and people answer the questions. Probably the ANDA people are not the same people that are reviewing, they're reviewing the ANDA, and yeah, but probably they missed it.

Page 190

Q. Okay. So putting aside your speculation that they missed it when they were looking, if a chemist at the FDA had reviewed the DMF setting forth the steps of the TEA with quenching process that listed triethylamine and sodium nitrate, should that chemist have identified that there was a risk for the formation of NDEA as of 2013?

MR. NIGH: Form objection, argumentative. Facts not in evidence.

A. I don't know, I don't know the answer to that.

Q. So it's your opinion that a chemist at ZHP should have looked at the process and expected it, but you can't say if a chemist at the FDA should have expected it if looking at the process?

MR. NIGH: Form objection, argumentative. Facts not in evidence.

A. I cannot speak on FDA's behalf, but I can tell you my experience dealing with manufacturing products. Our chemists, when we were manufacturing, for example, NVC-422, knew the chemistry of NVC-422 inside out and much, much more in depth than the reviewing chemists at the FDA. And we should have known that chemistry better.

Page 191

And that's how it is. FDA is reviewing, you know, five, ten applications every month. They can't be so engaged in that chemistry, whereas at ZHP and their contractors and who were involved in changing the process, they were knee deep involved in that chemistry. And, you know, all they had to do is look at the sodium nitrite and its use in food, and there is just huge body of data on the chemistry of sodium nitrite.

Q. Okay. But I'm just talking about, you say in your report that it's a well-known textbook reaction, that nitrosate triethylamine. So I understand your position that industry is more familiar with its own drugs, but if it's a well-known textbook reaction, shouldn't someone at the FDA have looked at that process and said this is a well-known textbook reaction that's going to create NDEA in 2013?

MR. NIGH: Form objection, argumentative.

A. Maybe, maybe not. Again, as I stated, and if somebody who is reading and looking at my testimony, they should go back. For the last five minutes, I've been repeating the same thing. FDA cannot be thorough as a manufacturer; and they are not.

Page 192

And that's fact and that's the only expected. We know more about our product than anybody else on the planet, and that's how it should be.

ZHP chemist, you know, Dr. Min Li admits that, you know, this chemistry happens, and Dr. Min Li, who is a ZHP chemist, admits that he was actually looking at nitrosation of, you know, various sartans back in 2015. So this is not novel. It wasn't novel to him.

Q. When did you personally first learn that TEA in the presence of sodium nitrate can react to form diethylamine that then diethylamine can react again with the positive nitrosonium ion to produce NDEA?

MR. NIGH: Form objection.

A. When I was engaged with this project, I immediately started looking at sodium nitrite and its potential problems. And basically, my guess initially for formation of NDEA was that there were some diethylamine impurities somewhere.

My thinking was in the process of making triethylamine, you can always have a little bit of diethylamine, and because the levels are so

Page 193

low, you're looking at nanogram quantities or in this case, thousands of nanogram quantities. You could have that much diethylamine impurity in triethylamine. But as I continued my investigation, I came across this chemistry, this reaction, that triethylamine also converts to diethylamine through nitrosation process.

Q. So through your investigation in connection with this litigation, you found the reaction. You initially -- that wasn't your first thought, though. Your first thought was that there must be some diethylamine contamination. You didn't go straight to the process?

MR. NIGH: Form objection.

A. Yes. My -- you know, my thinking was sodium nitrite, that -- immediately that jumped at me without doing any research because of the history of sodium nitrite. And then of course, you know, and I was trying to figure out how NDMA is being formed.

To form NDMA, you need dimethylamine. To form NDEA, you need diethylamine. So -- and it's very possible that triethylamine has some diethylamine as well.

Q. Okay. Are you aware of any --

Page 194

A. You need -- you need microgram quantities.
Q. Okay. Are you aware of any textbook that described the reaction of --
MS. ROSE: Oh, I'm getting an echo. Is anybody else getting an echo.
THE WITNESS: Getting an echo.
MS. ROSE: Is it still happening? It seems to have stopped. I'll go.
Q. Are you aware of any textbook that described this particular reaction of TEA reacting with a positively charged nitrosonium ion to then create diethylamine that then reacts again with a positively charged nitrosonium ion to create NDMA prior to 2018?
A. I'm not aware of a textbook, no.
Q. Are you aware of any article or scientific journal that documented that process prior to 2018?
A. Yes.
Q. And what is that article?
A. I will share that with you.
Q. This is the article that --
A. We did --
(Court Reporter Clarification.)

Page 195

A. We didn't -- we didn't cite it.
MS. ROSE: We didn't cite it, I think he said.
A. Yes, we haven't cited that article.
Q. Okay. All right. I want to go back a little bit to -- let's talk about NDMA for a little bit. Change it up. Okay. So I want to be clear. I'm talking about NDMA, not NDEA, at this point. We're switching.
Okay. So it's your opinion that the zinc chloride process, which is the process that was adopted in December of 2013 through DMF amendment, can result in the formation of NDMA. Correct?
A. Right.
Q. Okay. And is it your opinion that the zinc chloride process can result in the formation of NDEA?
A. If there's no triethylamine present, it shouldn't.
Q. And do you have any evidence that there was triethylamine present in the zinc chloride process?
A. No.
Q. All right. So let's talk about how NDMA can form during the zinc chloride process. I

Page 196

guess maybe I'll take it down generally.
Do you agree that NDMA is formed when a positively charged nitrosonium ion reacts with diethylamine [sic]?
A. Yes.
Q. So both a nitrosonium ion and dimethylamine --
MS. ROSE: I'm sorry. If I said diethylamine in my last question, I meant to say, Ellen, dimethylamine. We will write down these terms for you later.
Q. Okay. So I'll start my question again.
Both a positively charged nitrosonium ion and dimethylamine must be present in order to form NDMA. Correct?
MR. NIGH: Form objection.
A. Correct.
Q. Okay. I want to look at Figure 1A-3 on page 25 of your report. That is Tab 7.
This is the synthetic route of changed process zinc chloride. Is that correct?
A. What page is this?
Q. I'm sorry, was that a question?
A. I said: What page?
Q. Oh, I'm sorry, on page 25. It's up on

Page 197

the screen right now, on your Zoom screen.
A. Okay.
Q. And it's page 25 of your report.
A. Right.
Q. So this is the synthetic route for the zinc chloride process. Right?
A. Right.
Q. And dimethylamine is not part of this process. Correct? It's not mentioned anywhere here?
A. That's correct.
Q. Okay. But you need dimethylamine to form NDMA. Correct?
A. That's right.
Q. Okay. So how does dimethylamine become involved in the zinc chloride manufacturing process?
A. So DMF, you know, there's some residual amount of dimethylamine in DMF.
Q. You're referring to the DMF solvent. Correct?
A. I'm looking at DMF solvents.
Q. Okay.
A. The DMF solvent is dimethylamine attached to a carbonyl hydrogen --
(Court Reporter Clarification.)

Page 198

A. Carbonyl hydrogen. I'm sorry, I'm sorry, so it's just -- I think you should just write down DMF contains residual dimethylamine.
Q. Okay. So it's your opinion that the DMF solvent used in the zinc chloride process in itself contains dimethylamine.
A. So DMF will contain some dimethylamine and even if it doesn't contain dimethylamine, by simply heating it or exposing it to acid or base, it forms dimethylamine.
Q. Okay. So correct me if I'm wrong. It feels like that's too separate opinions.
One is that DMF solvent, when ZHP receives it, has dimethylamine contamination in it, and the other is that DMF solvent, when received by ZHP and then used in the zinc chloride process, decomposes into dimethylamine.
Are you offering both of those opinions?
A. That's correct.
Q. You're offering both?
A. That's correct. So in my opinion, there is a good possibility that DMF comes with some residual dimethylamine and it all depends on how old that actual DMF is. As a function of time and

Page 199

temperature, DMF breaks down into dimethylamine and probably carbon dioxide.
But if you -- my second opinion is that if you heat DMF, you're gradually going to generate dimethylamine. My third opinion is that if you expose DMF solvent to acid, it's going to generate dimethylamine.
My fourth opinion is if you expose DMF to a base, it's going to generate dimethylamine. You've got four things.
Q. I missed that last word. You said if you expose --
MS. ROSE: Ellen is nodding.
Q. If you expose dimethylamine to --
A. If you expose DMF solvent to an organic base, like sodium hydroxide, you're going to generate dimethylamine.
Q. Okay.
A. And heat, heat can exacerbate these interactions. And that is -- I do have a citation there, and I hope it's a good one there, in my report.
Q. Are you talking about the Purification of Laboratory Chemicals by Armarego on page 26?
A. That's correct.

Page 200

Q. Okay. Great. We'll get there in second. I just want to make sure.
So all four of those opinions, are those all included in your report here?
A. I believe so.
Q. Okay. So you believe you opined in your report that DMF solvent, when exposed to a base, decomposes.
A. Acid or base.
Q. Okay. I thought the third opinion was -- sorry. Let me make sure I understand.
One, the first opinion is that DMF, when a pharmaceutical manufacturer gets it, has dimethylamine in it. It just over time, no matter what you do, DMF will decompose over time into dimethylamine. Is that correct? That's one?
A. Very small quantity as a function of time.
Q. Okay.
A. The second opinion is that --
Q. Hold on. I want to pause. Hold on. I want to pause because I want to talk about that opinion.
So do you have a citation for the opinion that DMF solvent always decomposes into

Page 201

dimethylamine over time even without heat? Is there a citation for that in your report?
A. So when a product becomes heat-sensitive, it's just a matter of temperature. So if it's heat-sensitive at hundred degree, it's also heat-sensitive at room temperature.
Q. Okay. And do you have a cite for that in your report?
A. This common -- common knowledge in chemistry.
Q. It's common knowledge in chemistry that if a substance degrades at a certain temperature, it will degrade -- it will always degrade at temperatures below that temperature over time?
A. Degrades slowly. You know, so it's really a function of rate and how fast. It's a function of rate of reaction.
Q. Okay. Well, you know what? Maybe the best way for us to do this --
A. You know, if I -- if I -- if I basically put meat on the table, gradually it's going to go bad. If I heat it, if I put exposed higher temperature to that meat, it will go bad faster. Essentially if you keep something cool, it will last longer. And this is very true in this

Page 202

case as well.
If DMF has a propensity to generating dimethylamine as a function of temperature, then at a lower temperature it will also generate some dimethylamine but at smaller amounts.
Q. Okay. So I just -- I'm trying to figure out the best way to go through these opinions, because I think some of them are a bit new.
Why don't we look at -- you said that the cite you have, that DMF solvent -- here, let's just go to page 26 of your report. And let's go to the -- under the first heading, it says: "Using DMF solvent in the process should have raised concern for the possible formation of nitrosamines because DMF solvent has been long known to decompose into dimethylamine." That's where you cite the Armarego publication. Correct?
A. Correct.
Q. So that's your support for the opinion that DMF solvent can decompose into dimethylamine, one, over time or, two, with heat. Correct?
A. Correct.
Q. And when did you first become aware of this publication?

Page 203

A. I can't recall.
Q. Okay. Do you recall reading it before you became an expert in this litigation?
A. No.
Q. Did you first come upon this Armarego publication through a litigation search, or did someone provide it to you?
A. No, it was through the literature search.
Q. Okay. And did you personally perform that literature search or did someone else at Emery?
A. I don't recall. It might have been somebody else.
Q. Okay. If it was someone else, who would it have been?
A. Either Rakesh or Neil.
Q. Okay. All right. Well, I'll represent to you that this publication appears to be 743 pages.
Is it fair to say that you have not read the entire thing?
A. I think so.
Q. Sorry. You think you have read all 7 --
A. I have not read -- I have not read

Page 204

700 pages.
Q. Okay. How did you select the pages that you were going to review?
A. I came across the citation by the author. Specifically, I think -- if you bring that citation, it specifically talks about DMF and its degradation and its heat sensitivity.
Q. Okay. We'll get there. I just want to ask some questions about the document generally.
Do you know if any undergraduate or graduate-level chemistry programs use this publication as a textbook?
A. No, I don't.
Q. Have you ever cited this publication in any of your own published work?
A. I don't believe I have.
Q. Do you believe that every reasonable chemist would be familiar with this text?
A. I -- you know, Purification of Laboratory Chemicals, some variation of this is in every -- in every undergraduate textbook. It's used in the lab, in the teaching lab. So it doesn't have to be specific to this, but I have one on my desk, Purification of Laboratory Chemicals, by some other author. You know, so those are -- this is -- this

Page 205

is like a textbook.
Q. Okay. The Purification of Laboratory Chemicals that you have on your desk, did you look in that to see if there was anything about DMF solvent decomposing into dimethylamine?
A. No.
Q. Why not?
A. Didn't need to.
Q. Okay. Does -- sitting here now, do you recall if this Armarego publication expressly states that DMF solvent has long been known to decompose into dimethylamine?
A. I have to -- you know, show me the Armarego, you know, specific -- specific sentence.
Q. I'm heading there next. Again, we're on a mind melds, Dr. Najafi.
Okay. We're going to go to Tab 19, and we're going to go to page 66 which is page 76 of the PDF. You know what? Nope, nope, ignore me. It's not -- maybe I'm right.
We're going to go to page 192, which is page 206 of the PDF.
Do you see at the bottom there's the DMF entry?
A. Right.

Page 206

Q. Okay. Great. All right. The first line that says: "DMF decomposes slightly at its normal boiling point to give small amounts of dimethylamine and CO."

Do you see that?

A. Yes, carbon monoxide.

Q. Are you aware of DMF's boiling point?

A. Yes, I am.

Q. What is it?

A. 153 degrees Celsius.

Q. Do you know the highest temperature that occurred during the Step 4 of the zinc chloride process?

A. Not right off -- right offhand, but I think it was probably around hundred degrees since they had water.

Q. Okay. So lower than the boiling point of DMF. Correct?

A. Correct.

Q. And the Armarego text says that DMF will only slightly degrade at its boiling point. Correct?

A. Correct.

Q. And it doesn't say anything about DMF decomposing at lower temperatures?

Page 207

A. So as mentioned to you before, if something degrades at 150 degrees Celsius, it will also degrade at 60 degrees Celsius.

Q. But is that stated in Armarego?

A. It doesn't have to. This is, this is well understood. If something degrades at 153, you know, if I heat sugar at a hundred degree and caramelize it, and if I heat at 40 degrees Celsius, it's going to get brown. Not going to get caramelized, but it's going to get brown.

Q. And if you were to put sugar at 98 degrees, would it --

A. It's going to get -- it's going to go from light brown, dark brown, and then it gets completely decomposed into a caramelized situation.

Q. How long would that take?

A. I'm not a good cook. You know, sugar, you know, I would think within minutes.

Q. At 98 degrees --

MS. ROSE: Sorry, Ellen, I thought we were talking about Fahrenheit.

Q. Are you talking about Celsius?

A. No, we're talking about Celsius.

Q. You're talking about Celsius, okay. I'm going -- ignore my question.

Page 208

I guess my point is, you're saying it's just well understood that if something degrades at a high temperature, over time it will degrade at a low temperature as well. That's just well understood, and there's no need to provide a citation for that?

A. Gradually, gradually. So something really goes bad at 200 degree Celsius, it will start going bad at -- gradually it starts to degrading at, you know, even lower temperature. That's why you want to refrigerate the product. That's why pharmaceutical industry puts things in the freezer.

Q. Okay. And have you -- do you have any citation that would support the notion that DMF at the temperature in which the zinc chloride process was run degrades?

A. I don't have any citations offhand, but you can take my word to bank. That, you know, if it degrades at 153, it will gradually degrade, very gradually degrade at 30 degrees, 40 degrees Celsius.

What was the temperature of the process?

Q. I think you offered that it was a hundred degrees. I will represent to you that it's my understanding it was 137 degrees Celsius, but --

A. Okay.

Page 209

Q. -- either way.

A. It's coming close to the --

Q. So my point is you said it will take a longer time. So I guess my point is do you have anything -- what is the basis for your opinion that DMF will decompose over time at the temperature used in the zinc chloride process and how long that degradation would take?

A. I cannot give you exact answer on this, but it is -- as I mentioned to you before, this is well-known fact that if it degrades at 153 degrees, if it starts generating, according to the author here, it decomposes slightly at its normal boiling point.

When an author says "slightly," it means it could decompose 1 percent. Now, if you have, you know, if you have hundred grams and you get, you get half a percent decomposition at 153, and let's say you get .1 percent decomposition at the temperature that your client is using, you're talking about, you know, quite a few -- you know, you're talking about -- yeah, even half -- half a gram.

Half a gram translates into 500 milligram, which is 500,000 microgram, and add

Page 210

another three zeros, it will be nanogram. So you're going to have plenty of NDMA, plenty of dimethylamine forming for that nitrosonium ion to attach.

Q. But that's all based, again, on an assumption -- you just were using all those numbers on an assumption that DMF can degrade at the temperature used in the zinc chloride process within the time frame of the zinc chloride process, within the time frame that that process is being run for.

Do you have anything to support --

A. Right.

Q. -- the notion that that decomposition can happen within that time frame?

A. No, I don't, but you want to also read the second sentence of the author: "The decomposition is catalyzed by acidic or basic material so that even at room temperature, DMF is appreciably decomposed if allowed to stand for several hours with solid KOA, sodium hydroxide calcium hydride. We're talking also acid.

And what do we have in our chemical recommendation? We have hydrochloric acid. We have pH of 1 even at room temperature.

Q. Sorry, I was about to ask you about

Page 211

that sentence.

So this is saying that it can decompose at room temperature if allowed to stand for several hours with solid KOH, NAOH, or CAH2. Is it your position that during the sodium chloride process, DMF stood for several hours with those solids?

A. Zinc chloride process, you mean.

Q. If I said something different, I apologize, but yes, I meant zinc chloride.

MR. NIGH: Form objection. Hold on. Form objection, incomplete reading of the sentence.

You can answer.

A. It is my opinion that your client's process involved an acidic media and heat, and based on this document, the purification of organic compound, the decomposition is catalyzed by acidic media even at room temperature --

Q. Okay. But that didn't answer --

A. -- to the dimethylamine.

Q. That didn't answer --

A. You keep saying you didn't answer my question. You know, I did answer your question.

Q. All right. Well, I will rephrase the question, then.

I'm asking if it is your opinion that

Page 212

the zinc chloride process involved DMF standing for several hours with solid KOH, NAOH, or CAH2.

MR. NIGH: Form objection.

A. You're not reading the previous sentence: "Decomposition is catalyzed by acidic." What is acidic? What is acid? Do we have hydrochloric acid in the process? I'm asking you.

Q. All right. I'm not answering questions here. So if you want -- if you want to answer the question, then that's fine.

A. Then I'm answering the question. The decomposition of DMF is catalyzed by an acidic media which your client has in the zinc chloride process. And there's DMF and there's sufficient -- sufficient thermal pressure on the system.

I'm not surprised that dimethylamine is being generated under those conditions. We don't need half a percent. We actually need .0001 percent degradation to yield, you know, 10,000 nanogram of NDMA.

Q. But you can't say with any certainty what degree of degradation there may have been of DMF at the temperature and conditions in the zinc chloride process?

A. I cannot tell --

Page 213

MR. NIGH: Form -- hold on, Doctor. Dr. Najafi, hold on.

Form objection.

You can answer.

A. Your client can answer that question by doing a proper root-cause analysis. Knowing -- knowing this methodology, it could take some DMF, it could take some sodium nitrite, it could take some acid and heat it and see if NDMA gets generated.

Q. Okay. And it's your position that ZHP, in 2013, should have known to do that testing to look for NDMA based on what is set forth in Armarego. Is that correct?

A. This textbook was published I don't know when, but sometime in 1990s, or maybe earlier. I think it's a second edition. So it might have been 1980s. And this is a cookbook. This a recipe book for lots and lots of chemists to use to purify things and learn from.

And I have a different version from a different author. Basically, ZHP should have started investigating by doing risk analysis when they changed the process from tributyltin azide, when they changed the branded drug process to something else and they completely ended up changing

Page 214

the process, in my opinion, especially the penultimate process, penultimate step, they should have said: What's the impact of sodium nitrite? If they had just Googled it, they don't even need to go to Google Scholar or they don't even need to go to SciFinder.

If they had just Googled "sodium nitrite chemistry," you get a lot of information on sodium nitrite. And immediately they would have been worried about NDMA and NDEA and diisopropyl and mono isopropyl, all kinds of --

(Court Reporter Clarification.)

A. NDEA and other nitrosamines.

Q. Okay. I want to follow up on that.

So again, we're going off of DMF decomposition, and you're saying that ZHP should have been testing for NDMA based solely on the use of sodium nitrite in the process, putting aside anything to do with DMF composition?

MR. NIGH: Form objection.

A. When we have approved process, let's say, or a process gets approved at Sanofi-Aventis, Rhône-Poulenc Rorer and we change the process, every change we make gets scrutinized. And in this case, it was not scrutinized. I can tell you that much,

Page 215

that they didn't even do a Google search --

Q. Okay.

A. -- for sodium nitrite.

Q. That's fine, Dr. Najafi. But I know you have dinner plans. I'm trying to get you out for dinner.

I'm just asking the question. You brought it back to sodium nitrite.

So I'm saying, is it your position that any pharmaceutical manufacturer, in 2013, who used sodium nitrite in their manufacturing process needed to be testing for NDMA or NDEA?

MR. NIGH: Form objection, asked and answered.

A. Any pharmaceutical product, in my opinion, that was made post 1979, I won't even go to 1990s or 2000s, post 1979, if they used sodium nitrite, they should have been worried about NDMA and various other forms of nitrosamine.

Q. Okay. I believe -- I could be misremembering, but I believe you said earlier that it's the sodium nitrate plus an amine that creates a problem. But now you're just saying it's just the sodium nitrate. And as soon as -- as soon as you have sodium nitrate, to follow cGMP, you need to

Page 216

test for NDMA or NDEA.

MR. NIGH: Form objection, misrepresenting.

A. Nina, amines are everywhere. You know, they're everywhere. Every drug you're taking, there's some nitrogen moiety in it, you know, from lisinopril to Lipitor to what have you.

And so we're using triethylamine, dimethylamine. We're using a lot of different amines as either intermediates, as reagents. So, you know, yes, I think it's a very simple thing. They just need to be concerned about when they use sodium nitrite. They should be concerned about formation of some form of nitrosamine.

It doesn't have to be NDMA. It can be other nitrosated compound. It could be a nitrosated valsartan, which Dr. Min Li actually alluded to in his -- in his 2015 email from -- internal email. I've cited him in my report.

Q. Okay. So your point is that amines can be anywhere. So if you are making a pharmaceutical product and you are using sodium nitrate, you need to be looking for nitrosamines.

A. Sodium nitrite.

Q. Sodium nitrite. I apologize if I

Page 217

pronounced it wrong.

But is the answer yes to that question, if I had said it right?

A. Yes. If you're using sodium nitrite, you must be doing some investigation, you know, and looking to what's going on, what's happening with various impurities. And the easiest place to look for some of the volatile nitrosated compounds is by headspace GC. It cost probably 50 bucks to test it.

Q. Okay. And is there any FDA regulation or guidance that suggests that any process using sodium nitrite should be evaluated for the formation of nitrosamines?

A. I believe there is, you know, a, you know, guidance from IARC, International Association For Cancer. They actually recommend doing, you know -- you know, nitrosating agent, testing. It goes back to the seventies, and many, many drugs were tested, you know, for nitrosation potential. It's IARC. I've actually cited it, I believe.

Q. Oh, if you could show where you cited it.

A. NAP testing.

(Court Reporter Clarification.)

A. IARC.

Page 218

Q. And you cited?
A. Google -- not Google. Search for IARC.
Q. I'm sorry, you're asking me to search in your report for IARC?
A. Do you want me to search for it?
Q. Let me see. Let's look.
A. Let me just quickly -- it's page 8, page 8. I'm referencing IARC.
Q. All right. I apologize. I'm looking -- oh, are you talking about page 7?
A. Page 7, yeah.
Q. Okay. Hold on. Let me try to find that.
When did you first read this IARC monograph that you cite on page 7 of your report?
A. When did I first read it?
Q. Yeah.
A. Probably sometime -- I came across it back in -- God knows, probably sometime in 1990s once. And then I came across it during the Zantac project.
Q. Okay. Have you read the entire monograph?
A. Oh, for God's sake, no. God's sake, good bedtime reading.

Page 219

Q. Okay. So it's -- I want to go to -- let's see -- page 7 of your report what you cited it for. You say -- okay, let's see.
"Nitrosamines are simple organic compounds that include a nitroso group, NO+, bonded to a nitrogen." I'm -- yes, thank you.
"These compounds are a class of chemical compounds with the general structure R1, R2, N-N=0. Nitrosamines can form from secondary and tertiary amines by a relatively" --
(Court Reporter Clarification.)
Q. Oh, I'm so sorry.
"Nitrosamines can form from secondary and tertiary amines by a relatively simple chemical reaction which has been known for many years."
That's you writing in your report, and then you're citing to the IARC monograph. So --
A. Yes.
Q. Okay. You're not citing IARC for the proposition that anytime sodium nitrite is used in a manufacturing process, cGMP requires you to look for NDMA?
MR. NIGH: Form objection.
A. IARC essentially educates the chemist that nitrosation with sodium nitrite is a

Page 220

possibility. That's what I said. So this actually -- in fact, IARC provides guidance for -- they call it nitrosate -- it's a NAP testing and it's a nitrosating ability something testing, where back in the day, they actually looked to see what drugs are -- can easily be nitrosated.
So sodium nitrite was used for that kind of testing, and this was -- you know, back in 1970s, this was a big deal. And so it's been known for -- you know, for 50 years.
Q. All right. But I want to go back to my original question, which was whether any FDA regulations or guidance require you to look for sodium nitrite -- sorry -- required you look for nitrosamines anytime you were you using sodium nitrite in a reaction. And I believe the answer is no. Am I correct?
A. As far as I know, there was no guidance, but the only guidance is the IARC guidance and various -- in various forms where they talk about cohorts of concerns.
And as early as -- I believe 2015, there's a draft guidance, and then of course prior to that, there's concerns about nitrosamine and nitrosating agent or essentially volatile

Page 221

nitrosamines.
Q. But none of the ICH guidelines specifically say if you are using sodium nitrite, look for nitrosamines?
A. You cannot legislate science. You know, I think if you create guidance and guidance and guidance, pretty soon nobody is going to pay attention to anything. You can -- you cannot legislate common sense and science. You know, they say this is a genotoxic compound. You can't -- you have to look for it and you have to test for it, and that .1 percent doesn't apply to genotoxic. That's what it is.
Q. Wouldn't a pharmaceutical manufacturer need to know that an impurity below 0.1 percent was genotoxic to know they have to look for it?
MR. NIGH: Form objection, asked and answered.
A. I mean, it's going back to the same question we had two hours ago, targeted analysis versus untargeted analysis. The manufacturer -- the API manufacturer does risk analysis, looks at -- you know, they ask themselves, we're changing the process. Instead of tributyltin azide, we're now adding sodium azide. This is new. And then instead

of, you know, quenching it with X, now we're quenching with sodium nitrite.

Well, let's look into sodium nitrite, let's look into sodium azide. We're changing solvents. Let's look into solvents. You know, just saying, you know, we didn't know, we couldn't tell, you know, doesn't get you off the hook, you know.

So they needed to do proper risk analysis by qualified synthetic organic chemist. They would have been able to predict that it should be looking for nitrosamine and they would have probably managed to control it and saved a lot of money and a lot of headache.

Q. Okay. Well, you just made a point. It would have saved a lot of money and headache. Don't you assume that if ZHP had reason to believe that NDMA or NDEA was going to form from its processes, it would have tested for it to save the time and the headache?

MR. NIGH: Form objection, argumentative.

A. Well, you know, I think it goes back to not conducting a very proper risk analysis. If they did a risk analysis, it was a white wash.

MS. ROSE: Can I take a break for a

couple of seconds?

MR. NIGH: Sure.

MS. ROSE: Looking out for you too.

THE VIDEOGRAPHER: The time is 3:53. This ends Media Unit Number 4. We are going off the record.

(A brief recess takes place.)

THE VIDEOGRAPHER: The time is 4:38. This begins Media Unit Number 5. We're back on the record.

MR. NIGH: I just wanted to make a representation that Dr. Najafi had previously testified that he would get a document during the break, and my understanding is he has that document.

Go ahead, Ms. Rose.

THE WITNESS: I didn't even have -- I didn't even have time to go to the bathroom, just to let you know.

A. But, if you could kindly -- so, you know, I put in a link in my report. I think it was the wrong link. The correct link -- I actually have three citations to share with you, Nina. It's in the -- it's in print form. So I think the best thing to do is to give you the title of the article, and you can Google it.

Q. Okay. I'd -- sorry, before you do that, I just want to -- for the record. We went off the record about 45 minutes ago, and you found new documents that were not included in your report or on your reliance list of materials considered. Correct?

A. That's correct.

Q. And you're providing those --

A. And --

Q. Sorry, I'm still talking. You're providing those documents to me and to the defendants for the first time at 7:39 p.m. Eastern Time in your deposition which started at 12:00 p.m. Eastern Time. Correct?

We can talk about how to transfer them, but I'd like to go off the record to do that because I don't want to waste more time here. And I have not seen these documents before, so I'm probably going to need some time to look at them. I'm not a chemist and I can't review those documents super quickly, so we're going to have to take a pause here. This is brand-new material I have not seen before.

Okay, so why don't we pause and let's talk about how to transfer me the documents and then

we'll go from there.

THE VIDEOGRAPHER: The time is 4:40. We're going off the record.

(A brief recess takes place.)

THE VIDEOGRAPHER: The time is 4:55. We're back on the record.

MS. ROSE: I just want to state for the record what's happening. Right after the last break, Dr. Najafi came back from a break and said that he was going to provide three additional sources that support his opinions that are not in his report or on his reliance list that had not been disclosed to defendants.

We went on to a break so that Dr. Najafi could provide those materials. He provided one PDF document that is 11 pages long. He also provided two links to publications that are not available online for -- that are not available online without purchase. Only the abstracts are available.

I just want to make the record -- Dr. Najafi subsequently indicated that he is only relying on the abstracts.

BY MS. ROSE:

Q. So my question is, Dr. Najafi, number

Page 226

one, while we were on the break and you were looking for documents, did you speak to anyone?
MR. NIGH: Hold on one second.
A. I did, I spoke to --
MR. NIGH: Hold on, hold on, Dr. Najafi. I get to respond to that colloquy.
First off, the defendants asked certain questions. He's allowed to answer fully to those questions. He even asked, "Do you want me to find that document?" And defendants on the record said -- defense counsel responded "yes."
And so during the break, he found documents that were responsive to the testimony that he was giving, and that's why he has these documents now. I don't know that it's a full list of every single document that would be responsive to this sort of testimony.
But now, Dr. Najafi, you can answer the question.
MS. ROSE: Hold on. I want to respond to that. I'll ask the question again.
Just to clarify, I was asking Dr. Najafi about a cite in his report that he provided in his report. I showed him a cite in his report. He told me that cite was incorrect, and he

Page 227

did not intend to rely on that document. He intended to rely on another document.
It was not -- he did not raise documents in response to my questioning on topics that were not in his report. He specifically said he was replacing a document in his report. Just want to make that clear.
So my question was when you were -- we went off the record for you to look for this document, did you speak to anyone during that break while you were looking for the document.
MR. NIGH: To be clear on that representation, the document that he cited is still relevant as he explained. It's relevant to statements that are above. But I do agree that he said he wanted to replace the cite there with other documents and asked you if you wanted those documents and if he should find those during a break, which he did.
Q. Dr. Najafi, while you were on the break looking for documents, did you speak to anyone?
A. Very briefly with Rosemarie and Daniel.
Q. Okay. The documents that you -- your counsel has since provided to defendants, where did you get those documents?

Page 228

A. All three of them are online. One of them actually is a ZHP document that Rosemarie pointed out to me. The other two are abstracts that are published, and they're available to us.
Q. Okay. So let's talk about the ZHP documents. And I -- I cannot upload it right now because I -- we haven't yet had the time for us to upload it to the system. But the PDF document that you say is a ZHP document, you say Rosemarie, one of the plaintiffs' lawyers, directed you to it.
Did she send you the document?
A. Yes.
Q. Okay. And that document had not previously been in your files?
A. I believe it's been in my files, in my Dropbox files.
Q. Okay. But you didn't include it in the reliance list that you said you created.
A. No, I meant to -- you know, I should have included it. It was miscited. They're -- actually, Nina, there are probably two dozen things that I could cite regarding the formation of [audio distortion].
(Court Reporter Clarification.)
A. Two dozen potential citations regarding

Page 229

what Nina is asking for. So I think we can rely on just one of them.
Q. Okay. But you didn't include any of those two dozen in your report or in the reliance list that you said that you created?
A. It was mistakenly wrong article was cited. Although it was a relevant article, it was azide, sodium azide, but it was not the appropriate one for what I was trying to show.
Q. Are you going to release an amended report that relies or cites to these documents that you have just now produced to defendants --
MR. NIGH: No.
Q. -- a couple of hours into your deposition?
MR. NIGH: No, he doesn't need to.
Q. But, Dr. Najafi, that was a question for you.
MR. NIGH: I can answer that as his counsel. The answer is no.
THE WITNESS: I had to discuss with, yeah, with the counsel.
Q. Okay. So the first document that's a ZHP document, counsel just provided to you. And the other two are links to abstracts that are available

Page 230

online.
Where did you get those abstracts?
A. On PubMed.
Q. When did you call up those abstracts?
A. Now.
Q. For the first time?
A. I just did, yeah.
Q. They were --
A. No, no, no. One of them, one of them is an article that -- he's a very famous guy -- had already seen this, and you could rely on that. Loeppky, he's been doing nitrosamine work for many, many years; I've seen it. But I pulled it online right now.
Q. Did you rely on that article that you just pulled online now when you were writing your report that you submitted October 31st?
A. Yes, I have.
Q. And when was the first time you saw that article? And tell me the name of it again?
A. It's -- Loeppky is the author, and the name of the article is "Ester-mediated nitrosamine formation from nitrite and secondary or tertiary amines."
Q. And did you -- when you say you relied

Page 231

on that document, did you rely on the entire article or just the abstract?
A. So I've had -- I have the entire article; I just cannot find it right now.
Q. So you relied upon the entire article in forming your opinions?
A. Right, exactly.
Q. And for the other link that you sent me, I believe that's an article called "Theoretical investigation of N-nitro dimethylamine formation from nitrosation of trimethylamine." Right?
A. Yes.
Q. Did you rely on that whole article or just the abstract?
A. Basically I just relied on the abstract.
Q. You did not read the whole article?
A. No.
Q. Okay. And when was the first time you read that abstract?
A. I just -- the first time.
Q. Today was the first time you read that abstract?
A. Yes.
Q. So you did not consider that document

Page 232

when you were forming your opinions in October 2020?
A. It is -- we can drop this off altogether because my opinion is primarily formed on Loeppky and, you know, on the document from ZHP. You know, there is another -- Nina, there's another two dozen articles that you can find on this that I haven't reviewed, but, you know, they're relevant to your question.
Q. Sorry, documents that you haven't reviewed, you're saying. There's two dozen documents you have not reviewed?
A. Yes.
Q. Okay. But those documents, you're not relying on forming your opinion. Those are just anonymous documents that exist?
A. Yeah, but they prove the same facts.
Q. Okay. But you have not disclosed those to defendants at any time?
A. No.
Q. No. Okay.
And you do not rely on them in writing your report?
A. No.
MS. ROSE: So I want to say on the record, Dr. Najafi has testified that he relied on

Page 233

the entire article of the Loeppky article --
THE WITNESS: Loeppky.
MS. ROSE: -- and plaintiffs have not disclosed that to defendants. We cannot question him on that document if we don't see the whole document that he reviewed when he was forming his opinions.
So I'm going to have to state right now I'm going to have to hold the deposition open until we receive that document. We reserve the right to question him on that document. And then I am going to go off --
MR. NIGH: We can argue about that later. I think we can move on to the other topics at this point.
MS. ROSE: Okay. I'm going to need to go off the record because I haven't had the chance to review the ZHP document that you just disclosed to us. So I'm going to have to go off the record so I can look at that to decide if I'm able to ask you questions given how late you disclosed it.
MR. NIGH: It's also been utilized in multiple other depositions.
Q. But it was not cited in your report or reliance list, correct, Dr. Najafi?

Page 234

A. I'm not sure. I have to go to my report and check.
MS. ROSE: Okay. Let's go off the record. Thank you.
THE VIDEOGRAPHER: The time is 5:05. We're going off the record.
(A brief recess takes place.)
THE VIDEOGRAPHER: The time is 5:22. We're back on the record.
MR. HARKINS: Just for the record, this is Steve Harkins with Greenberg Traurig for the Teva defendants. On behalf of the finish dose manufacturers, including Teva and Torrent, we would like to note for the record that significant time with this witness has now been used out of the standard seven hours for examination as a result of these documents that were produced.
We also have not been able to review and evaluate whether there's any questioning required of this witness pertinent to these documents and specific allegations against finish dose manufacturers.
Dr. Najafi has indicated that he has opinions specific to the finish dose manufacturers, and though we have about an hour and 20 minutes of

Page 235

total questioning left, I suspect that we may need to seek additional time beyond that again due in no small part to this issue with obtaining documents.
We can deal with that when it comes, but I believe we're going to have a back off the record so that we can all take a look at the additional material that Dr. Najafi has provided.
MR. NIGH: I understand your position, Mr. Harris [sic]. I do want to raise -- just to make clear that on the break before these documents -- before Dr. Najafi searched for these documents, we got a time check, and at that time, it was five hours and 28 minutes on the record. That was before any of the questioning about the documents.
MR. HARKINS: Understood. We can go back off.
MR. NIGH: Yes.
THE VIDEOGRAPHER: The time is 5:23. We are off the record.
(A brief recess takes place.)
THE VIDEOGRAPHER: The time is 5:43. We're back on the record.
MS. ROSE: I just wanted to state on the record I echo Mr. Harkins' comments that ZHP

Page 236

feels it's inappropriate for Dr. Najafi to disclose new scientific materials as support for major assertions of his report at the end of a lengthy deposition.
ZHP has not had appropriate time to review the scientific materials and determine which questions are necessary or appropriate.
Also, ZHP's experts have not had the opportunity to review these materials, offer opinions on them. They may need to expand on their opinions based on these newly disclosed materials that were not included in Dr. Najafi's report.
In addition, the ZHP defendants, before these materials were disclosed, had planned to ask other questions of Dr. Najafi. They have not allocated time to discuss these documents because we were not aware of them until the end of the deposition.
At this point, we feel we need to ask our other questions, and we're going to move forward, and we are reserving the right to seek more time with Mr. Najafi -- sorry -- Dr. Najafi to ask about these newly disclosed materials that were not included on his report or on his reliance list. And with that, I can move forward with our questioning.

Page 237

MR. NIGH: I'll put something on very briefly. As stated previously by Dr. Najafi, he couldn't rely on any one of these three documents to establish the principles that he cited in his report, and one of the documents is a document that has been used in multiple other depositions. So the experts or whoever else is helping defendants prepare for these depositions would have had access to that document, especially since it's been used at other expert depositions as well.
MS. ROSE: I'll just state in response that defendants' experts cannot be expected to anticipate that Dr. Najafi or any other plaintiffs' expert may be relying on any document that's been produced in this litigation or has been used in a deposition if it is not included in his report or on his reliance list earlier in the deposition.
He specifically testified that his opinions were based on the materials that were included in his report and on his reliance list and that he selected the materials for his reliance list.
MR. NIGH: We can continue.
MR. HARKINS: I'll simply second what Ms. Rose said on behalf of the finish dose

Page 238

manufacturers. Thank you.
MS. ROSE: All right. Dr. Najafi, with that aside, you can finish listening to lawyers talk to each other, and I will ask you a few more questions.
I'm going to introduce Tab 38.
(Exhibit Najafi-13, Novartis Testing Monograph for Valsartan, Bates ZHP02214602 through 2214671, was received and marked for identification.)
COURT REPORTER: And this is document?
MS. ROSE: I want to say we're at Exhibit 9.
THE VIDEOGRAPHER: 13.
MS. ROSE: Oh, 13. Oh, wow. Time flies.
Q. Okay. Dr. Najafi, this is the Novartis testing monograph for valsartan. Correct?
A. Right, yes.
Q. Have you seen this document before?
A. Yes, I have.
Q. And you're aware this document is on your list of materials considered?
A. Yes, I am.
Q. If you turn to page 19 of the document,

Page 239

not the PDF, page 19 of the document, the document page numbers are on the top right-hand corners of the page.
Do you see on page 19 that the Novartis testing monograph provides for GC-FID testing for residual solvents?
A. Yes, I do.
Q. Okay. Great. Oh, and can we go back to page 1 of the document for a second? If you look at the very bottom, it says: "Approved" -- sorry. "Approved for report publication by Flavin Aine -- I'm going to try to pronounce this -- Ringaskiddy at Wednesday, April 25, 2018."
Correct?
A. Okay, yeah.
Q. So we can go back to page 19.
So according to the Novartis testing monograph for valsartan, as of April 2018, Novartis was using GC-FID to test valsartan. Correct?
A. That's correct.
Q. On that same page, it lists various reagents and one of them is DMF. Correct?
A. Yes, that's correct.
Q. Does that mean that Novartis was testing for a DMF as part of its valsartan testing?

Page 240

A. Reagents, solvents, I -- I would not know. These are some of the reagents they're using. I don't know how they're using DMF.
Q. Is it your interpretation of this document that Novartis was using DMF as part of its testing process?
MR. NIGH: Form objection.
A. It looks like -- it looks like it. It looks like they're testing for ethyl acetate, benzene, methanol, ethanol, toluene, DMF, tert-butyl-methyl ether, and of course there's another solvent, it looks like, 1-methylpyrrolidone. So it looks like they're testing for these.
Q. Okay. So Novartis had reason to expect that DMF might be a part of -- I'm sorry. I'll restate the question.
It shows that Novartis was aware that DMF might be present in valsartan?
A. This is -- I don't -- you know, this is -- Novartis is the manufacturer, original manufacturer of valsartan. So the question is, is this -- you know, the product, is this the monograph they're using that was used for manufacture of, you know, basically valsartan, you know pre- -- pre-ZHP or not? I assume it is. They're just using that

Page 241

same monograph.
Q. So you think that Novartis was testing for DMF in the original valsartan brand-name drugs?
A. You know, I don't know. I think what you want to do is let me actually take a look at the full document, if you don't mind. Could you put that -- put the link on chat --
Q. You have --
A. -- whoever is managing the chat? The link has disappeared.
Q. Dr. Najafi, you have access -- you have access to the whole document.
A. Oh.
Q. Oh, are you no longer able to access the document, sir?
A. I'm no longer.
Q. All right. Let's go --
A. Every time we go into the --
MS. ROSE: Let's go off the record.
THE WITNESS: Every time we go in the break room, we lose it.
THE VIDEOGRAPHER: The time is 5:50. We are going off the record.
(A brief recess takes place.)
THE VIDEOGRAPHER: The time is 5:54.

Page 242

We're back on the record.
MS. ROSE: Ellen, can you read the pending question.
(Question read back.)
A. It looks like, you know, this document shows that they're testing for DMF.
Q. Okay. And I believe you previously stated that you thought this monograph was the same monograph that they used for the -- when I say "they," Novartis used for the testing of its original brand name Exforge and Diovan. Correct?
A. I cannot confirm or deny that.
Q. Okay. But this does show that as of April 2018, Novartis was aware that DMF was likely to appear in valsartan?
MR. NIGH: Form objection.
A. That's something you have to ask Novartis.
Q. But I'm asking you if the testing monograph is testing for DMF, doesn't that suggest that Novartis expects DMF to be present?
MR. NIGH: Form objection.
A. Obviously they have knowledge that DMF is present and they're testing it, so that's what it looks like.

Page 243

Q. And there's a -- you're saying there's a possibility that Novartis was using the same monograph when it was testing its name brand Diovan and Exforge?
MR. NIGH: Form objection.
A. It's the possibility.
Q. Okay. And if that is correct, if assuming that they were using this monograph when testing Diovan and Exforge, that would mean that they were expecting that DMF might be present in those name brand drugs?
MR. NIGH: Form objection.
A. You're putting hypothetical thing over hypothetical things. You know, I don't know. I don't have the answer. Again, that's a question for Novartis. But from the monograph itself, it looks like they have DMF as one of the components they're going to be testing for.
Q. Okay. And you tested earlier that -- sorry, you testified earlier that it's basic science that DMF can decompose into dimethylamine even at room temperature?
A. Dimethylamine.
Q. Dimethylamine. I apologize, it's late here.

Page 244

A. DMF, you know, so they're -- they're looking for DMF in this -- in this sample they're testing. It looks like they are -- they have DMF as -- you know, they're targeting DMF, so this is a targeted analysis. They have selected series of solvents, and they're looking to -- for their measurements.
Q. Okay. And they've only selected one, two, three, four, five, six, seven, seven specific solvents out of all the solvents in the world?
A. Right.
Q. They're looking for those seven?
A. Exactly.
Q. So there must be some expectation that those seven might appear in valsartan?
MR. NIGH: Form objection.
A. Exactly. So that's a targeted analysis. I'm going to go over here.
MS. ROSE: I just want to state for the record that Dr. Najafi just got up from his chair and walked away.
A. I'm turning on the heater in my room. It's getting a little cold. Sorry.
Q. No problem. No, just let me know. Let me know. I don't think you're running away. You've

Page 245

given up.
A. Okay. Yeah, no, no.
Yeah, so it's a targeted analysis, it looks like.
Q. You've previously taken the position that you believe Novartis conducted appropriate testing for valsartan. Correct?
A. I believe so.
Q. And you have no issue with the testing set forth in this monograph?
A. Not -- no, I think, I looked -- I've actually looked at this before. This is where Novartis is actually testing three matches of valsartan from -- from your client, and this is a batch that -- this is where they find lots of impurities in valsartan batches using GC-FID, and then they send it to Sovias for further -- further characterization.
Q. Okay. I just wanted to make the point. I'm just asking about this document. I'm asking about the valsartan testing monograph, Novartis's valsartan testing monograph.
You have no criticisms of the testing set forth in that document?
A. No.

Q. Okay.
MS. ROSE: We can move to Tab 14.
(Exhibit Najafi-14, FDA Document entitled "Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients, Guidance for Industry," No Bates, 58 Pages, was received and marked for identification.)
Q. This is ICH Guidance Q7, "Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients." Correct?
A. Yes.
Q. And the date on this is September 2016. Correct?
A. Correct.
Q. And okay. And this is what you cited in your report. Correct?
A. Yes.
Q. If we go to page 1 of the document, not the PDF, but the document number and in the center bottom of the page.
In the first paragraph, would you agree that Q7 states that it is "...intended to provide guidance regarding good manufacturing practice (GMP) for the manufacturing of active pharmaceutical ingredients (API) under an appropriate system for

managing quality"?
MS. ROSE: Are you okay, Ellen?
COURT REPORTER: Yes, thank you.
Q. Do you agree with that statement?
A. Yes, I do.
MS. ROSE: And if we go to -- let's go to PDF 33, which I believe is page 27 of the actual document. Perfect.
Q. In the last paragraph but midway through, do you agree that it states specifications and test procedures should be consistent with those included in the registration filing?
A. Yes.
Q. So ICH Q7 doesn't set forth any specific testing protocols for API itself, does it?
A. No, it doesn't. Last I checked, it's really a very general, you know, sort of overview of, you know -- but they do have a section on contaminants. You know, they do talk about a lot of different, you know, potential issues that could arise.
Q. Dr. Najafi, does Q7 state that drug substance manufacturers must demonstrate that their process is not at risk for forming nitrosamines?
MR. NIGH: Form objection.

A. I don't believe so.
Q. Do you know if the term "nitrosamine" or "nitro" appears anywhere in Q7?
A. For the same reason that cyanide doesn't appear in this document. Cyanide is also poisonous, and lots of other -- dimethyl sulfate is possibly worse than nitrosamine. Doesn't appear on this document either. So just the mere fact that something doesn't appear doesn't -- doesn't make it good.
Q. Let's turn to page 29 of the document. I believe that's PDF page 30 -- I actually don't know. You've got it, so it doesn't matter.
Okay. The first sentence is: "An impurity profile describing the identified and unidentified impurities present in a typical batch produced by a specific controlled production process should normally be established for each API."
Correct?
A. Yeah, that's correct.
Q. So Q7 assumes that there will be some impurities in a drug substance?
I'm sorry, I want to correct myself.
It assumes that there will be some unidentified impurities in a drug substance?

A. That's correct.
Q. And it assumes that there will be impurities in general in the substance. Correct?
A. That's correct.
Q. In your report, you cite Q7 for the proposition that "If a manufacturing process cannot be modified to stop nitrosamines from forming, that a purification or elimination step should be added along with testing to verify the step was successful and nitrosamines do not remain."
Does ICH Q7 specifically state that?
MR. NIGH: Form objection.
A. ICH Q7 does not specifically mention this, but there are plenty of guidances that, you know, mention that -- you know, the control of impurities, whether it's .1 percent or .001 percent, if they are genotoxic, then all bets are off. And there are plenty of documents I've cited in my report. There's ICH M7. There's various guidances from the FDA and all that.
Q. But ICH Q7 doesn't say that?
MR. NIGH: Form objection.
A. I'm not sure. We have to look at ICH M7. Oh, M7 does that.
Q. I'm sorry. I said -- I was just

Page 250

confirming that ICH Q7, which -- the document that we're looking at and that you just took time to review, that ICH Q7 does not say that?

MR. NIGH: Form objection.

A. Q7 -- you know, I'm on Q7. "Appropriate specification" -- this is -- I'm taking -- I don't know where it is on this thing on the document. It's page 34. "Appropriate specification" -- let me just read this for a second, I don't want to bother Ellen --

THE WITNESS: Ellen, don't write.

MR. NIGH: No, she has to write.

THE WITNESS: Okay, I'm just reading it. I'm just reading it, sorry.

MS. ROSE: Do you want to go off the record so you can read it?

MR. NIGH: No, no, no. He's reading it out loud in response.

THE WITNESS: Quickly.

MS. ROSE: I don't think he's reading it out loud. I think he's reading it to himself.

MR. NIGH: You're right.

MS. ROSE: Can we just go off the record?

MR. NIGH: No, no. He's ready to

Page 251

respond.

THE WITNESS: No. Please, please, let's -- "Appropriate specification should be established for API in accordance with accepted standards." And accepted standards -- our accepted standards are no mutagen in a drug that we're going to be taking for 30 years.

And consistent with the manufacturing process, the specification should include control of impurities, organic impurities, inorganic impurities, and residual solvent if API has specification for microbiological purity, blah, blah, blah. So of course ICH -- you know, ICH Q7 talks about impurity.

Q. I can't tell where you're reading from, Dr. Najafi, but it's okay. I don't want to belabor the point.

A. This is -- for the record, it's Exhibit 14, and Tab 14, ICH Q7, FDA September 2016.

Q. Yeah, I know which document we're on.

A. And it's page -- page 34.

Q. Page 34 of the document or the PDF at the bottom of the document?

A. Oh, at the bottom of the document, let me look.

Page 252

No, I'm sorry. It's page 28 on the document, at the top of the page. This document -- for the record, impurities are mentioned ten times in this document. I basically searched it.

Q. Okay. So it's your position that the first paragraph on page 28 of Q7 is -- supports -- sorry, I'll start over.

It's your position that the first paragraph of page 28 of Q7 stands for the proposition that a purification or elimination step needs to be added to a manufacturing process along with testing to verify that nitrosamines do not remain.

Is that your position that it's there in that paragraph? Correct?

A. Also -- yes, also on page 29, for the record, an impurity profile describing the identified and unidentified impurities present in a typical batch produced by a specific control production process should normally be established for each API.

The impurity profile should include identity or some quantitative analytical designation retention time, the range of each impurity observed and the classification of each impurities in

Page 253

organic -- organic solvents, the impurity profile is normally dependent upon the production process. The impurity profile is normally dependent upon the production process.

So when you change the production process, you're going to have changed impurity profile. So if you're -- if your client is using their old USP monograph as impurity profile, they're completely mistaken. And I'm not surprised that when, you know, Novartis ran their GC, they probably freaked out.

MS. ROSE: Okay. I think we've gone past responsiveness, and I would like to give Teva and Torrent their time to question. So I'm going to at this point go off the record so we can evaluate.

THE VIDEOGRAPHER: The time is 6:12. We're going off the record.

(A brief recess takes place.)

THE VIDEOGRAPHER: The time is 6:20. We're back on the record.

MS. ROSE: I'm going to pass Dr. Najafi to Mr. Harkins for some questioning on behalf of Teva and Torrent.

EXAMINATION BY MR. HARKINS:

Q. Good evening --

Page 254

MR. NIGH: If I may, I need to interject a couple of things here. I need to know if there's anybody else other than you that has any additional questions, other than -- other than in regards to the new documents that were produced today.

MR. HARKINS: I believe counsel for the other finish dose manufacturer defendant may also have questions after the conclusion of mine. I don't know the scope of those, but I suspect that there will be some.

MR. NIGH: Do you have any idea how long your questioning -- about how long you have for your questioning other than the new documents that were produced today?

MR. HARKINS: I hope to be able to complete my questioning with regard to topics other than the new documents that were produced today within the time. However, I'll note that some amount of time has, as I stated on the record before, been used dealing with those documents. The finish dose manufacturer defendant Torrent may also have further questioning, and if I speak a specific number to the world, I'm sure it will be inaccurate. So I would rather just keep going, if you guys don't

Page 255

mind.

MR. NIGH: No, I actually do mind. I'm just trying to get a sense because Dr. Najafi has let us know he's been here for nine hours and 20 minutes. You know, I'm trying to get a sense for how much longer you have. Irrespective of what the amount of time is for the seven hours, none of those arguments, just how much more time and questions do you think you have, your best estimate?

MR. HARKINS: Between the finish dose manufacturers, I would estimate an hour.

MR. NIGH: Hour total between Torrent and Teva?

MR. HARKINS: Pending specific responses that do not apply to both of the finish dose manufacturers from Dr. Najafi, I think that's fair, yes.

MR. NIGH: Okay. And does Torrent's counsel agree to that representation?

MS. ROSE: Yes.

MR. NIGH: I don't know who's here for Torrent counsel. Brittney. Brittney Nagle?

MS. NAGLE: Yes, so I think we will be able to fit within an hour along with Mr. Harkins' estimate, but we'll see.

Page 256

MR. NIGH: Okay. I think respectfully at this time, Dr. Najafi has been going for nine hours and 23 minutes. He's let me know it's been a long day. I agree. It's been a long day. I'm not faulting either side. I understand that there's a point where it took him some time, 45 minutes to find the documents, and it took others time to try to respond to those new documents.

But at this point he's tired. He would like to break for the day. I'd like to try to work on can we reschedule. He's let me know that on January 24th, he's available between 8:00 to noon. That's the only date that I could find that he's available before we take defense expert depositions.

So to the extent that in terms of the calendaring, if that time works, I'd like to be able to calendar that time on the books now and continue the deposition at that time.

MR. HARKINS: Can we jump to our breakout room and discuss -- and just to confirm, that's January 24th from 8:00 to 12:00 --

MR. NIGH: Pacific Time.

MR. HARKINS: I'm sorry. Pacific Time.

MR. NIGH: Pacific Time, 8:00 to noon.

MR. HARKINS: 8:00 to noon Pacific

Page 257

Time. Okay. Can we go to the breakout and -- I'm sorry. Go off the record?

MS. ROSE: Yeah, let's go off the record and then --

THE VIDEOGRAPHER: The time is 6:24. We're going off the record.

(A brief recess takes place.)

THE VIDEOGRAPHER: The time is 6:40. We're back on the record.

MR. NIGH: I just want to put on the record we're going to let the witness go. At this point he's let us know that it's nine hours and 40 minutes, and he's not going to be able to answer any additional questions. He's let us know he has fatigue at this point. And we agree to keep the deposition open. We are going to try and meet and confer as to timing and length.

Thank you, Doctor.

THE WITNESS: Thank you so much. Thanks, everyone. Bye-bye.

THE VIDEOGRAPHER: The time is 6:40. We're off the record.

(A brief recess takes place, and the following takes place off the video record.)

MR. NIGH: Steven, you want to go ahead

and put the proposal?

MR. HARKINS: Sure. This is Steve Harkins with Greenberg Traurig for the Teva defendants.

Per discussion with plaintiffs' counsel, the parties have agreed to resume the deposition of Dr. Najafi on January 24th at 8:00 a.m., Pacific Time. The defendants allotted two hours of total questioning time remaining on the record. I believe the parties are in agreement.

MR. NIGH: Yes. And my understanding is that the defendants have conferred, and they agree that that two hours of total time works for all three of the defendants, that they would split it up, they would meet and figure out how to split up that time, and that if I do have additional questioning, the time that they want to reserve for questions, say it's a half hour, they would -- that would come out of their two-hour block, that they would have that time after my questioning.

Is that agreeable?

MR. HARKINS: That's correct and agreeable.

MR. NIGH: Thank you, all. Appreciate it.

MR. HARKINS: Off the record?

MR. NIGH: Off.

(The proceedings concluded at 9:55 p.m.)

DANIEL NIGH, ESQ.
dnigh@levinlaw.com

January 20, 2023

RE: In Re: Valsartan, Losartan, Et Al
1/18/2023, Ramin (Ron) Najafi , PhD (#5661352)

The above-referenced transcript is available for review.

Within the applicable timeframe, the witness should read the testimony to verify its accuracy. If there are any changes, the witness should note those with the reason, on the attached Errata Sheet.

The witness should sign the Acknowledgment of Deponent and Errata and return to the deposing attorney. Copies should be sent to all counsel, and to Veritext at cs-nj@veritext.com.

Return completed errata within 30 days from receipt of testimony.

If the witness fails to do so within the time allotted, the transcript may be used as if signed.

Yours,
Veritext Legal Solutions

J U R A T.

I DO HEREBY CERTIFY that I have read the foregoing transcript of my deposition testimony and I certify that is it true and correct to the best of my knowledge.

SWORN AND SUBSCRIBED
BEFORE ME ON THIS
DAY OF 2023

Notary Public of the State of

ATTACH TO DEPOSITION OF RAMIN (RON) NAJAFI, Ph.D.:
IN THE MATTER OF: VALSARTAN

DATE TAKEN: January 18, 2023

E R R A T A S H E E T

INSTRUCTIONS: After reading the transcript of testimony, please note any change, addition or deletion on this sheet. DO NOT make any marks or notations on the transcript itself.

Please sign and date this errata sheet and return it.

PAGE	LINE	CHANGE

DATE and SIGNATURE:

C E R T I F I C A T E

I, ELLEN J. GODINO, LICENSE NO. X10l6l8, a Certified Shorthand Reporter of the State of New Jersey, do hereby certify that prior to the commencement of the examination, RAMIN (RON) NAJAFI, Ph.D. was duly sworn by me to testify the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a true and accurate transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

Ellen J. Godino

ELLEN J. GODINO
CERTIFIED COURT REPORTER
State of New Jersey
DATED: 1/20/22

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY. THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

Veritext Legal Solutions is committed to maintaining the confidentiality of client and witness information, in accordance with the regulations promulgated under the Health Insurance Portability and Accountability Act (HIPAA), as amended with respect to protected health information and the Gramm-Leach-Bliley Act, as amended, with respect to Personally Identifiable Information (PII). Physical transcripts and exhibits are managed under strict facility and personnel access controls. Electronic files of documents are stored in encrypted form and are transmitted in an encrypted fashion to authenticated parties who are permitted to access the material. Our data is hosted in a Tier 4 SSAE 16 certified facility.

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Inquiries about Veritext Legal Solutions' confidentiality and security policies and practices should be directed to Veritext's Client Services Associates indicated on the cover of this document or at www.veritext.com.